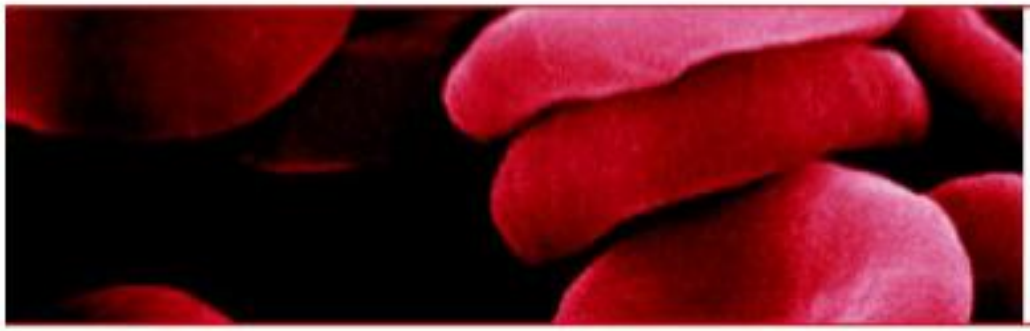
Mythic™ 22 AL



Orphée

User's Manual

Orphée S.A.

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Cod. M22AL/UM-EN/004

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03	04/08/10	HC	> 1.0	Update of the sections 3.4.3/3.4.1/3.4.4/5.10.1/7.2
04	13/08/10	HC	> 1.0	Add the Declaration of Conformity

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LOCAL AGENT

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WARNING
Important Safety Instructions

Must be read before attempting to install the product.

	CAUTION - RISK OF DANGER **Indicates a procedure to be strictly respected in order to avoid any risks for the operator (user) or damages on the instrument or on the quality of results.**
	CAUTION – BIOHAZARD RISK **Indicates that wearing gloves is mandatory before performing the described operation due to risk of contact with materials that may be infectious.**
	CAUTION – HOT SURFACE **Indicates hot temperatures surfaces and risk of burns**
	CAUTION – CLASS 2 LASER RADIATION **Indicates laser radiation and do not stare into the beam**
NOTA	**Indicates important additional information**

- The slots and openings in the back or bottom are provided for necessary ventilation. To ensure reliable operation of this apparatus or its DC adaptor, and to protect it from overheating, these openings must never be blocked or covered.
- Do not place this apparatus or its DC adaptor near or over a radiator or heat resistor, or where it is exposed to direct sunlight.
- Do not place a vessel containing liquid on this apparatus and its DC adaptor, as this can result in a risk of fire or electric shock.
- Do not expose this apparatus or its DC adaptor to rain or place it near water. If this apparatus or its DC adapter accidentally gets wet, unplug it and contact your service center immediately.
- Make sure to pull out the power cord from the outlet before cleaning.
- Do not overload wall outlets, extension cords or adaptors beyond their capacity, since this can result in fire or electric shock.
- Do not use travel power adapter
- Power-supply cords should be routed so that they are not likely to be walked on or pinched by items placed upon or against them.

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- To protect apparatus or its DC adaptor from a lightning storm, or when it is left unused for long periods of time, unplug it from the wall outlet. This will prevent damage to the set due to lightning and power line surges.
- Before connecting the AC power cord to the DC adaptor outlet, make sure the voltage designation of the DC adaptor corresponds to the local electrical supply.
- Never insert anything metallic into the open parts of the DC adaptor. Doing so many create a danger of electric shock.
- To avoid electric shock, never touch the inside of the DC adaptor.
- Make sure to plug the power cord in until it is firmly inserted. When removing the power cord, make sure to hold the power plug when pulling the plug from the outlet. Do not touch the power cord or DC adaptor with wet hands.
- If this apparatus does not operate normally – in particular, if there are any unusual sounds or smells coming from it – unplug it immediately and contact your service center.
- Be sure to contact an authorized service center, when installing your set in a location with heavy dust, high or low temperatures, high humidity or chemical substances. Failure to do so may cause serious damage to your set.
- Use only a properly grounded plug and receptacle. An improper ground may cause electric shock or equipment damage.
- To disconnect the apparatus from the mains, the plug must be pulled out from the mains socket, therefore the mains plug shall be readily operable.
- Do not install the product in an unstable location such as a shaky table or a location exposed to vibration.
- Do not drop or impart any shock to the product. If the product is damaged, disconnect the power cord and contact your service center.
- Always replace or use parts of the apparatus supplied by your service center.

- The MYTHIC 22 AL is an automated hematology analyzer for in vitro diagnostic to be used in clinical laboratories by an authorized people.
    - Only human blood or artificial control blood should be run.
    - Only the reagents mentioned in this manual are permitted to be used.
    - The optimum performances can be only achieved if the cleaning and maintenance procedures are carefully followed.
- All parts or surfaces of this apparatus could be potentially infective. Use adequate protection to prevent any risk of contamination (gloves, glasses, disinfectant).
- The elimination of waste supplied by this apparatus must be done in compliance with your local authorities.

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ATTENTION
RAYONNEMENT LASER DE CLASSE 2
EN CAS D'OUVERTURE NE PAS REGARDER DANS LE FAISCEAU
CAUTION
CLASS 2 LASER RADIATION
WHEN OPEN DO NOT STARE INTO THE BEAM

This equipment has an embedded class 2 laser product.

By removing the protect cover operator could have exposure to hazardous laser radiation.
Do not stare into the beam

All operations of service must be do after equipment is switched off.

Wavelength:	**650nm**
Beam divergence:	**54°**
Pulse duration and repetition rate:	**200 scans/s**
Maximum power:	**1mW**

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This equipment needs special precautions regarding general requirements for safety.

Guidance and manufacturer's declaration – Electromagnetic emissions		
The MYTHIC 22 AL is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 AL should assure that it is used in such an environment.		
Emissions test	**Compliance level**	**Electromagnetic environment - guidance**
Harmonic emissions IEC 61000-3-2	Class A	The MYTHIC 22 AL is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The MYTHIC 22 AL is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 AL should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MYTHIC 22 AL requires continued operation during power mains interruptions, it is recommended that the MYTHIC 22 AL be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration – Electromagnetic immunity			
The MYTHIC 22 AL is intended for use in the electromagnetic environment specified below. The customer or the user of the MYTHIC 22 AL should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MYTHIC 22 AL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150Khz to 80Mhz	3 Vrms	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 80Mhz to 2,5Ghz	3 Vrms	$d = 1,2\sqrt{P}$ 80MHz to 800MHz $d = 2,3\sqrt{P}$ 800MHz to 2,5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80Mhz and 800MHz, the higher frequency range applies. NOTE 2 Theses guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM an FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should considered. If the measured field strength in the location in which the MYTHIC 22 AL is used exceeds the applicable RF compliance level above, the MYTHIC 22 AL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MYTHIC 22 AL.

[b] Over the frequency range 150KHz to 80MHz, field strengths should be less than 3V/m.

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NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The user may find the following booklet, prepared by the Federal Communications Commission, helpful:
How to identify and Resolve Radio/TV Interference Problems. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-000-00345-4.
Pursuant to Part 15.21 of the FCC Rules, any changes or modifications to this equipment not expressly approved by C2

The symbol on the product indicates that this product may not be treated as household waste. Instead it shall be handed over the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information about recycling of this product, please contact your local city office or your distributor of this product.

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KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

Name und Adresse der Firma
Nom et adresse de l'entreprise
Nome e indirizzo della ditta
Name and address of the firm

Orphée S.A.
19 Chemin du Champ des Filles
1228 Plan Les Ouates

Wir erklären in alleiniger Verantwortung, dass
Nous déclarons sous notre propre responsabilité que
Dichiariamo sotto nostra responsabilità che
We declare under our sole responsibility that

das Medizinprodukt für die In-vitro-Diagnostik
le dispositif médical de diagnostic in vitro
il dispositivo medico-diagnostico in vitro
the in vitro diagnostic medical device

Mythic 22 AL
Ref. M22AL

mit folgender Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG
avec la classification selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE
con la classificazione secondo la direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

☐ Produkt der Liste A, Anhang II / Dispositif de la liste A, annexe II / Dispositivo dell'elenco A, allegato II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Dispositif de la liste B, annexe II / Dispositivo dell'elenco B, allegato II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist / Dispositif destiné à l'autodiagnostic non listé dans l'annexe II / Dispositivo per test autodiagnostico non elencato nell'allegato II / Device for self-testing not listed in Annex II
☒ Sonstiges Produkt / Autre dispositif / Altro dispostivo / Other device

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.

remplit toutes les exigences de la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE qui le concernent.

soddisfa tutte le disposizioni della direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE che lo riguardano.

meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

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Angewandte Gemeinsame Technische Spezifikationen, harmonisierte Normen, nationale Normen oder andere normative Dokumente Spécifications techniques communes, normes harmonisées, normes nationales et autres documents normatifs appliqués Specifiche tecniche comuni, norme armonizzate o nazionali applicate, altri documenti normativi applicati Applied common technical specifications, harmonised standards, national standards or other normative documents	IEC 60825-1:2007 IEC 61010-1:2001 IEC 61010-2-101:2002 IEC 61010-2-081:2001 and A1:2003 IEC 61326-2-6:2005
Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimentodi valutazionedellaconformità Conformity assessment procedure	Annex III
Konformitätsbewertungsstelle (falls beigezogen) Organe respons. de l'évaluat.de la conformité(si consulté) Organo incaric. della valutaz. della conform. (se consultato) Notified Body (if consulted)	N/A
Ort, Datum / Lieu, date / Luogo, data / Place, date Geneva, 10.08.2010	Name und Funktion / Nom et fonction /Nome e funzione / Name and function Tomasz Tuora CEO & President

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Orphée

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1. INSTALLATION

1.1 UNPACKING

1.1.1 Introduction

The **MYTHIC 22 AL** is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized and trained people.

- Only human blood or artificial blood (recommended control or calibrator) should be run.
- Only the reagents mentioned in this manual are permitted to be used.
- The optimum performances can only be achieved if the cleaning and maintenance procedures are carefully followed (see section 9.1).

	If the MYTHIC 22 AL has been stored at a temperature lower than 10°C it must be left at room temperature during 24 hours before power on.

1.1.2 Unpacking Procedure

Before unpacking the instrument, we recommend to check the box of the instrument and notify any damage to the carrier.

- Open the box on the top, remove the starter kit.
- Remove the **MYTHIC 22 AL** from the box.

Starter kit contents:

INSTALLATION KIT	
QTY	**Designation**
1	Tubing 23 - DILUENT
1	Tubing 24 - WASTE
1	150W DC adaptor
1	European Power line cord
1	MYTHIC 22 AL User's manual
1	Screwdriver Slot 1/4"
10	Racks

MAINTENANCE KIT	
QTY	**Designation**
1	Tubing 50
10	Silicon Sleeve
5	Tie wraps
2	Rinsing Head O-ring
1	Silicon grease (3gr)
1	Short Arm TORX T10 Tool
1	Short Arm TORX T20 Tool

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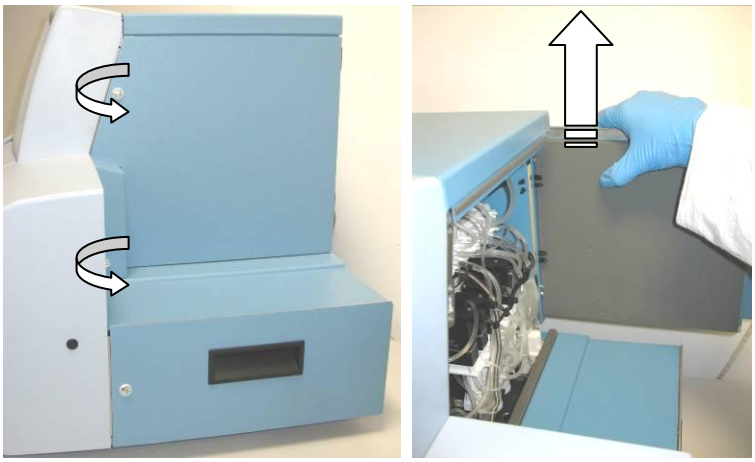
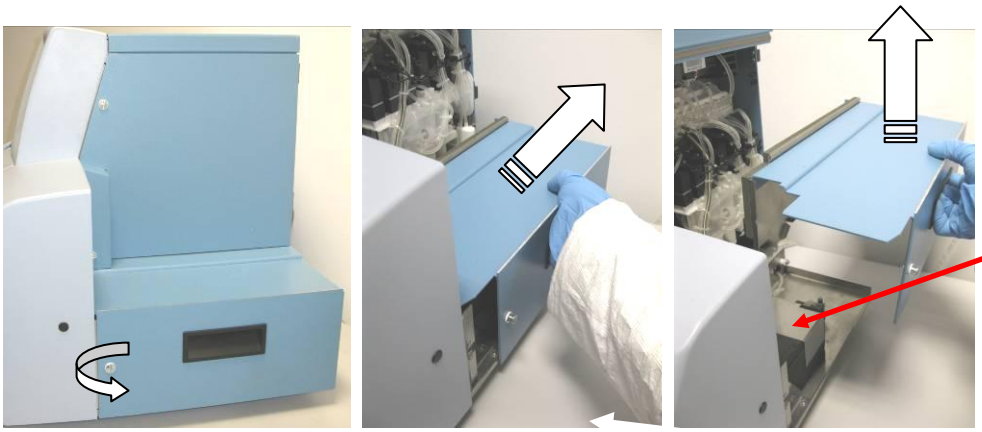
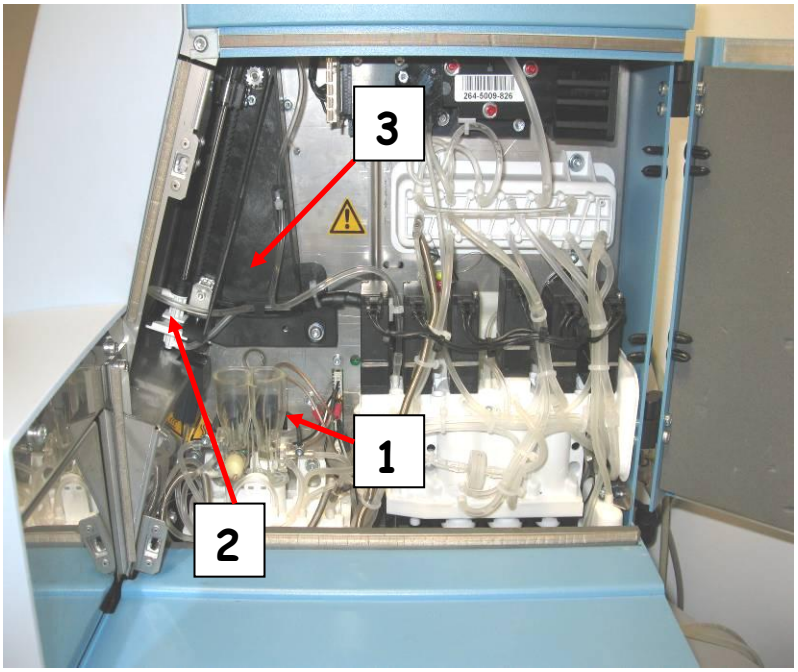
1.1.3 Visual checking



- Open the door on the right side by unscrewing the two quarter turn screws with the key provided in the kit.
- Open completely the door, then lift it to remove.



- Unscrew the two quarter turn screws with the key provided in the kit.
- To remove the unloading table, push to the back first then lift it.
- Check the good fixation of the air pump.



Remove the plastic wedge of the bath block.
To be checked:

1- Counting chambers perfectly locked in their manifold locations.
2- Needle's dismountable system located in the rocker.
3- Rocker in front position at the maximum course.

⚠	HAZARDOUS MOVING PARTS, BEWARE TO STAY AWAY FROM THESE PARTS WHEN THE MACHINE IS SWITCHED ON. THE BARCODE READER IS A LASER CLASS II; NEVER DISMANTLE THE COVER, IN CASE OF PROBLEM CALL ORPHEE REPRESENTATIVE.

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1.2 INSTALLATION CONSTRAINTS

1.2.1 Installation place

To ensure that the **MYTHIC 22 AL** fulfills its function, place the instrument on a table which supports the weight of the instrument, printer and reagents (~40 Kg). Leave a space of 10 cm at the rear of the instrument to ensure a well-ventilated place. Avoid a place that can be exposed to direct sunlight.

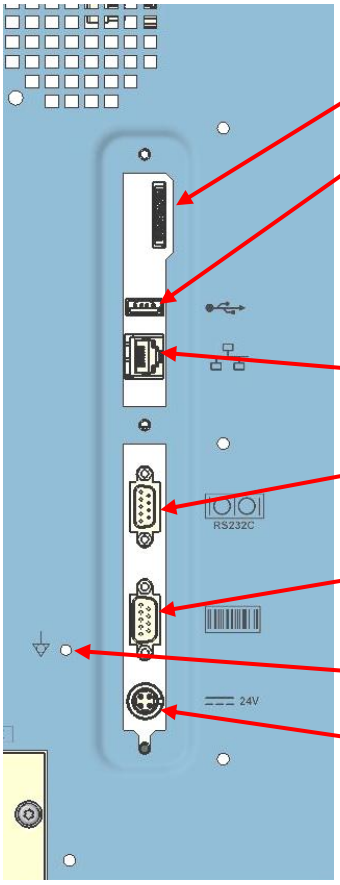
1.2.2 Installation environment

a) Indoor use;
b) Altitude up to 3 000 m (see NOTA hereafter);
c) Temperature 18 °C to 34 °C;
d) Maximum relative humidity 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C;
e) MAIN supply voltage fluctuations up to ±10 % of the nominal voltage;
f) Transient over voltages typically present on the MAIN supply.
g) Rated pollution degree II.

NOTA	Please contact Orphee's representative if you want to use the instrument in special conditions (altitude higher than 2000 m or special power supply conditions).

1.3 ELECTRICAL CONNECTIONS

1.3.1 Rear connectors



CONNECTION : SYMBOL :

- Not available
- 1 USB port:

⚠	**This USB port can be used <u>ONLY</u> for the printer connection.**

- Ethernet connection (TCP/IP):
- Host connection (RS232C):
- External barcode reader (RS232C):
- Equipotentiality:
- Power supply cord connection:

24V

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1.3.2 Front connectors

	Any output or input connections (except the printer and the barcode reader supplied by ORPHEE) cannot be done without the ORPHEE's representative authorization.

1.3.3 Power supply block

MYTHIC 22 AL must be connected to the power with the power supply block provided with the starter kit. Choose a well-ventilated place for the block and be sure to connect this power supply in a socket-outlet with a correct earth connection.
The power supply block must be placed at the rear of the **MYTHIC 22 AL** and, if possible, in an upper position to avoid the contact with any liquid.
To disconnect electrically the **MYTHIC 22 AL,** remove the power supply plug from the main circuit.

	In case of replacement of the main power wire, supplied with the MYTHIC 22 AL, the new one must comply with the local regulation (3×1.5mm cable and 250V 10A plug). **The MYTHIC 22 AL has been certified with the power supply provided with the instrument. If another power supply is used with the instrument, Orphee or its representative will not apply any warranty on this power supply and on the instrument. Please contact Orphee or its local representative before using such material.**

1.4 PRINTER CONNECTION

Connect the printer cable in conformity with the printer user's manual.

Use ONLY the rear USB plug ( ) of the **MYTHIC 22 AL** to connect the printer cable. Select the printer driver (section 3.3).

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1.5 CONNECTION, CHANGE AND PRIMING REAGENTS

⚠	**MYTHIC 22 AL works exclusively with the reagents described in section 4.3. Orphee or its local representative will not be responsible for the quality of the results and for the maintenance of the instrument if other commercial reagents are used.**

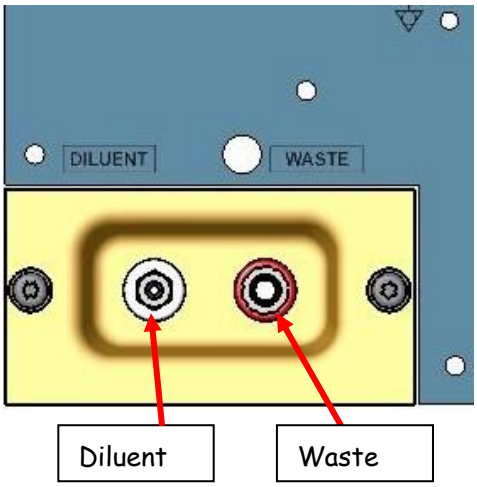
1.5.1 Connection

Lytic reagent and cleaning solution:

⚠	**Before handling the reagents, read carefully their specifications described in section 4.3 and check if their shelf life dates are not reached.**

- Remove the door on the left side of the instrument.
- Put the reagent bottles into the dedicated location.
- Remove the caps of the bottles.
- Tighten the red caps on the OnlyOne bottle (red sticker) and the blue one on the cleaning solution bottle (blue sticker).

Diluent and waste:



- Connect the diluent tube (male connector) on the outlet on the bottom and tighten the cap on the diluent container.
- To use 20 liters diluent container, add the tubing straw adaptor supplied with the installation kit.
- Connect the waste tube (female connector) on the outlet on the top and tighten the cap on an empty container.

⚠	**• Do not modify the type and the length of the diluent and waste tubes.** **• The diluent must be placed at the same level as the MYTHIC 22 AL.**

⚠	**It is mandatory to collect the waste in a container and to treat it in compliance with your local regulations.**

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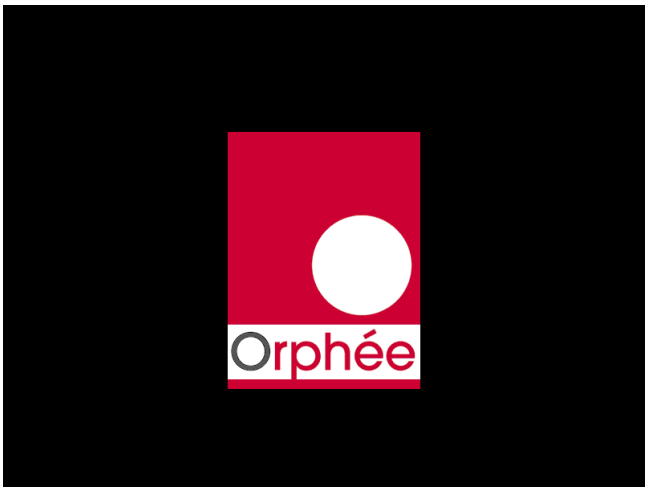
1.5.2 Priming

When using the **MYTHIC 22 AL for the first time**, it is necessary to perform a complete prime of the fluidic circuit. This operation should be done by a Field Service Engineer.

⚠	**Before starting, be sure that all the reagent and waste tubes are properly connected.** **The reagents must be stored 24 hours minimum at room temperature before use.**

Priming procedure:

① Switch on:

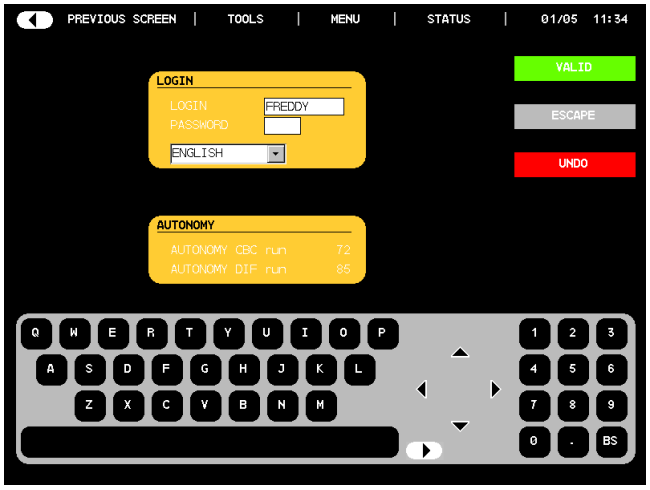


- Connect the power supply block (see section 2.3.4).

- Press the ON/OFF button.

- The logo Orphee appears during a few seconds.

② Login:



- The operator's identification display appears.
- Enter the user's identification, the password (see section 3.1).
- To validate or not the modification, see section 8.7.1.
- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller volume of reagents).

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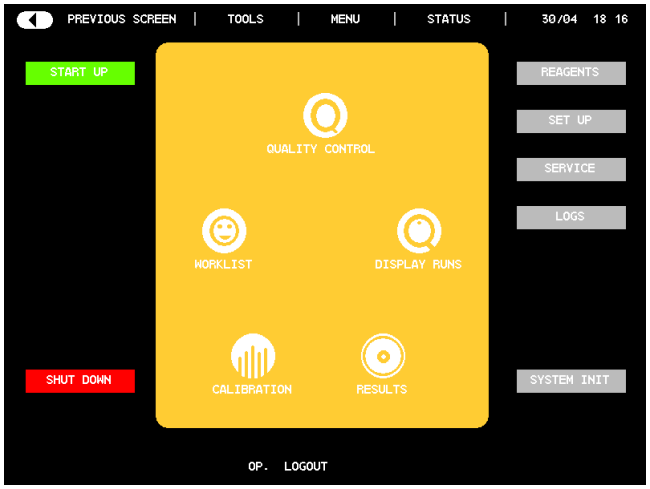
③ System priming:



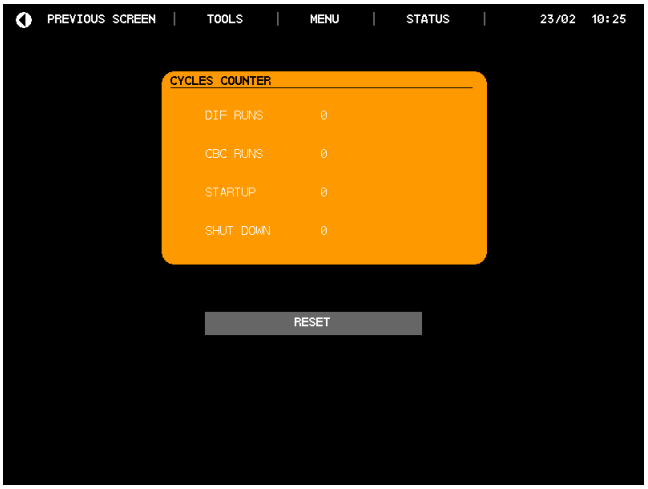
- The main menu is displayed.
- Press on REAGENTS.

NOTA	To do an emergency stop in case of problem push briefly on the on/off button

- Press PRIME ALL: The **MYTHIC 22 AL** performs a complete priming cycle.

- **AUTONOMY (run)** indicates the number of samples (runs).
- To prime or to know the quantity of reagent, press the dedicated button.

- Press CYCLES COUNTER to display the cycle counters.



- To reset the counter with the button RESET, please contact your Orphee's representative.

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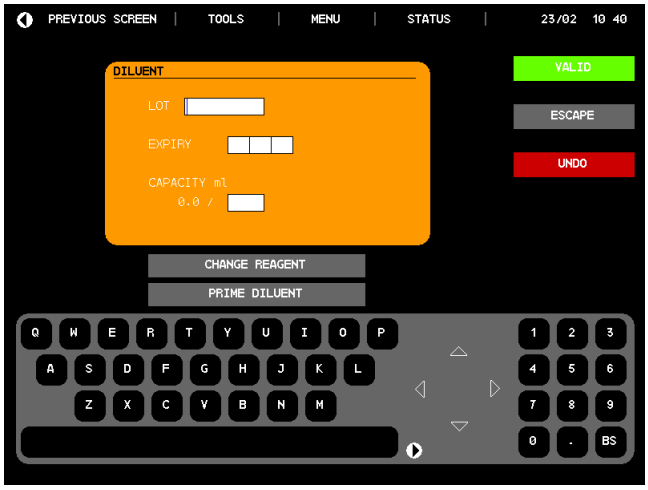
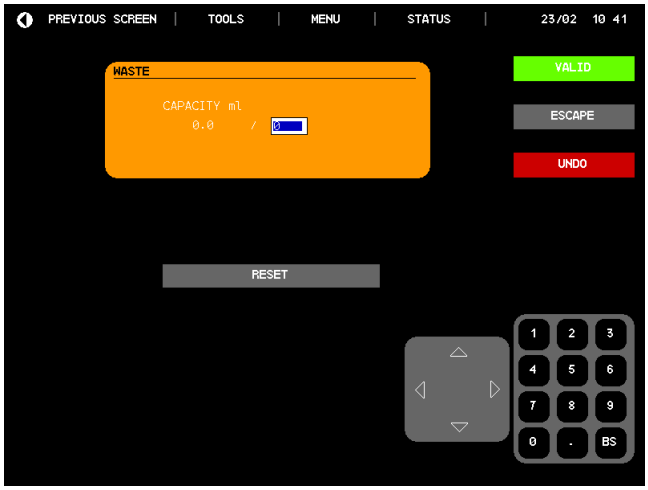
DILUENT PRIME:



- From the **MAIN MENU**, press REAGENTS then DILUENT to have access to this screen.
- Enter lot number, the expiry date and the container capacity.
- Press CHANGE REAGENT to validate the new entry or after changing a new container with the same information.
- If needed, enter the container volume in milliliter.
- After the replacement of a new container or to prime the diluent, press PRIME DILUENT
- A new entry is automatically done in the logs (see section 5.9)
- To validate or not the modification, see section 8.7.1.

LYSE AND CLEANER PRIME:
Proceed as described above for the diluent.

WASTE:



- Only enter the capacity of the container.

- After replacement of the waste container, press RESET to initialize the waste calculation.

- To validate or not the modification, see section 8.7.1.

MYTHIC 22 AL IS NOW READY TO OPERATE.

1.6 TRANSPORTATION AND STORAGE

Before transportation outside the laboratory, perform a complete cleaning with a disinfectant in compliance with the local regulations.
Storage temperature: -10°C to +50°C.
If the **MYTHIC 22 AL** has been stored at a temperature lower than 10°C, it must be left at room temperature during **24** hours.

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2. GENERAL OVERVIEW

2.1 INTENDED USE

The **MYTHIC 22 AL** is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories by an authorized and trained people.

- Only human blood or artificial blood (recommended control or calibrator) should be run.
- Only the reagents mentioned in this manual are permitted to be used.
- The optimum performances can be only achieved if the cleaning and maintenance procedures are carefully followed (see section 9.1).

2.2 GENERALITIES

MYTHIC 22 AL is a fully automated analyzer performing hematological analysis on whole blood collected on EDTA K2 or K3 tubes.

- Sampling volume: 18,2 µl (inside the needle, the total volume could be upper according to the blood remaining outside of the needle).
- Two sampling modes: - closed tube in 10 racks of 5 tubes
  - opened other vial in a special position (front door open)
- Throughput: close tube mode: > 40 samples/hour
  Other vial mode: > 45 samples/hour
- 22 analysis parameters in DIF mode and 12 parameters in CBC mode:

Leukocyte parameters:

WBC	White Blood Cells
LYM	Lymphocytes in % & # (DIF mode only)
MON	Monocytes in % & # (DIF mode only)
NEU	Neutrophils in % & # (DIF mode only)
EOS	Eosinophils in % & # (DIF mode only)
BAS	Basophils in % & # (DIF mode only)

Erythrocyte parameters

RBC	Red Blood Cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Blood cells Distribution Width

Thrombocyte parameters

PLT	Platelet
MPV	Mean Platelet Volume
PDW*	Platelet Distribution Width
PCT*	Thrombocrit

* For Investigation Use only in the United States of America

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2.3 OVERVIEW

MYTHIC 22 AL consists of 9 main parts:

1. Auto loader system
2. Display.
3. Dilution hydraulic part.
4. Mono electronic board.
5. Reagent tray.
6. Connection.
7. External power supply block.
8. Printer.
9. Barcode reader (option).

2.4 MAIN PART DESCRIPTION

2.4.1 Display

	Use only a soft paper to clean the screen, never use direct liquid otherwise the screen could be damaged.

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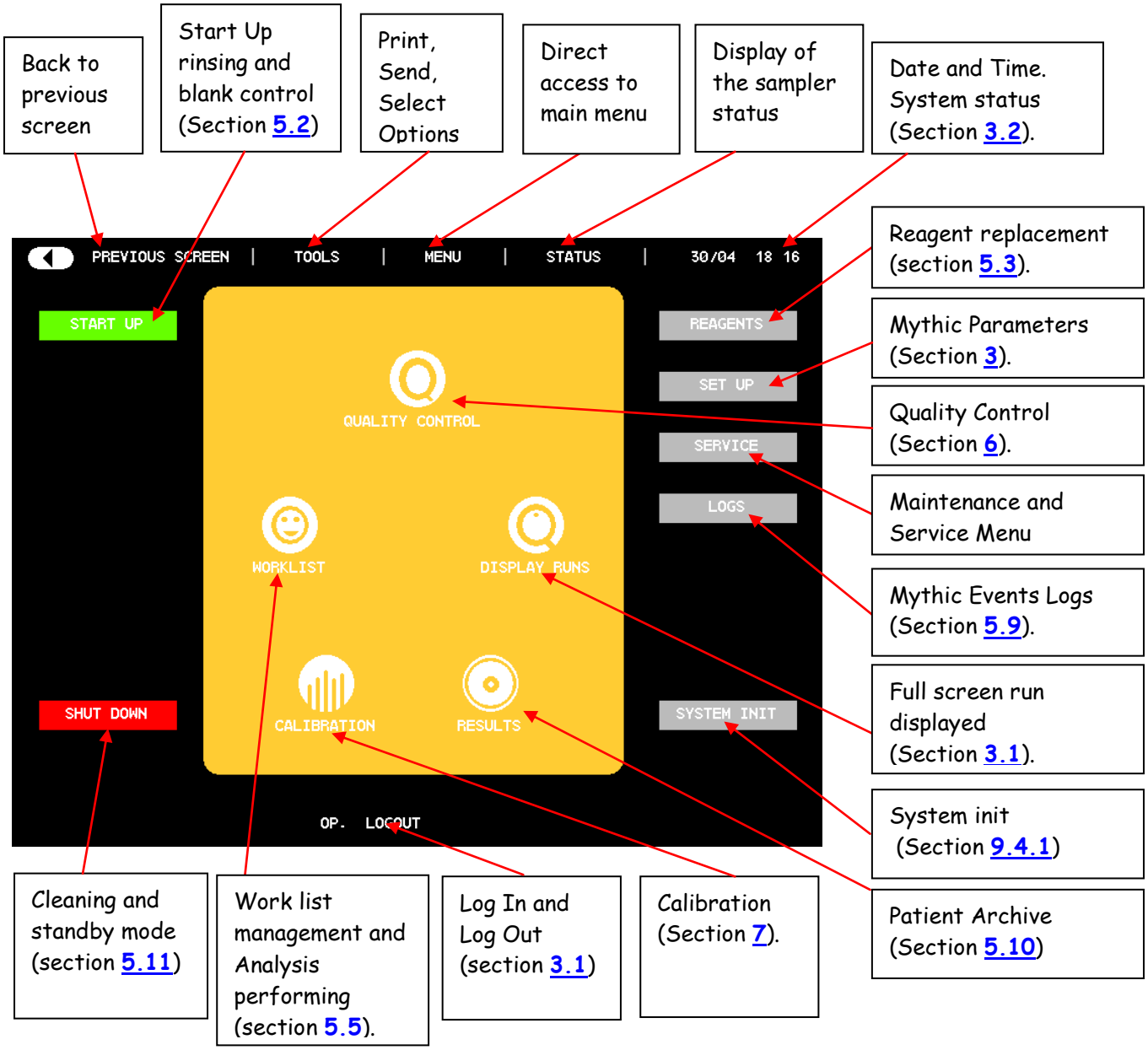
Main Menu description



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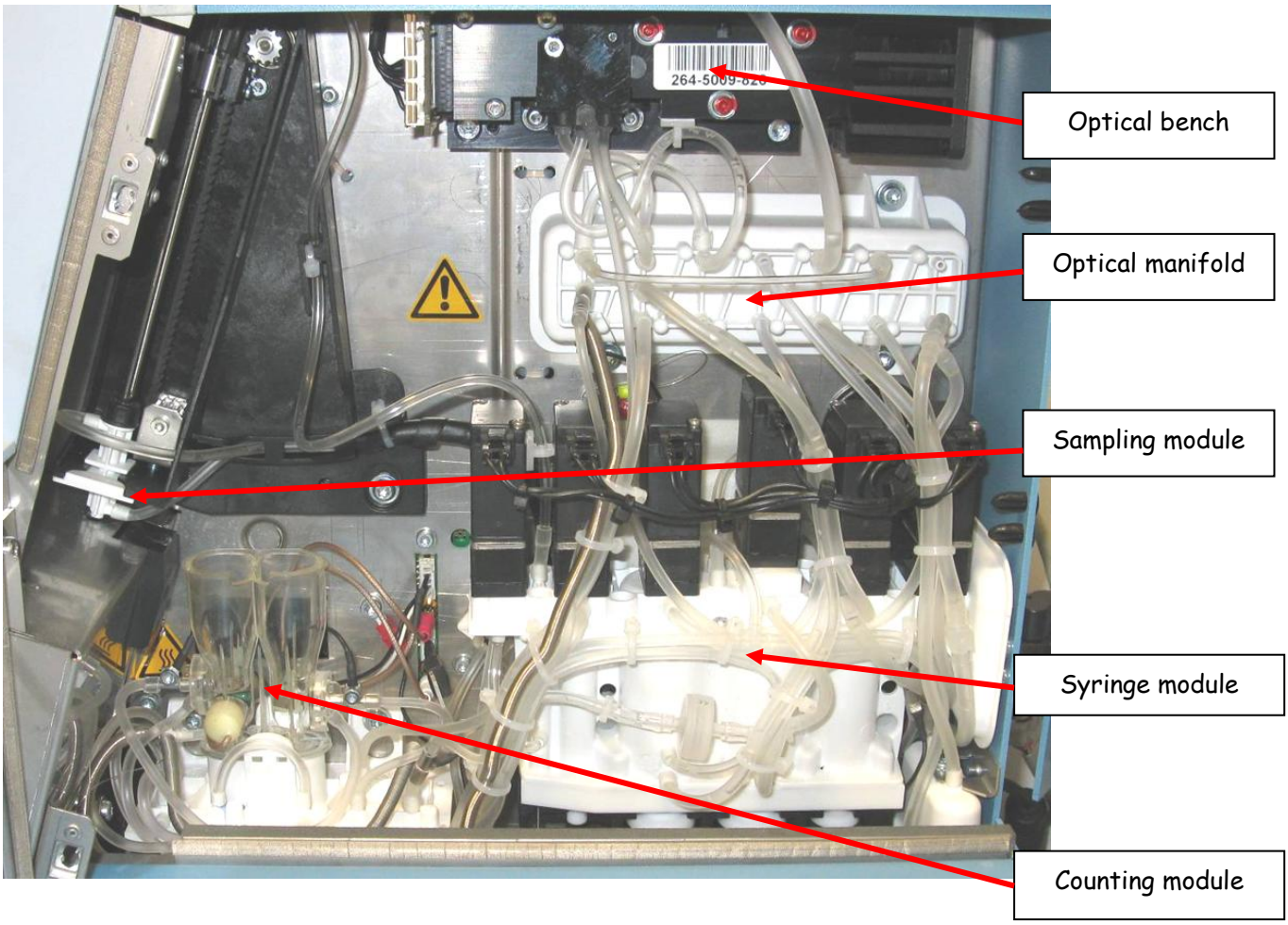
2.4.2 Dilution fluidic part

All the fluidic part is on the right side of the instrument and consists of five modules only:

- Sampling module :
  - Rocker (patented) : Manages the rise and descent of the needle.
- Syringe module (patented) consists of one block :
  - Reagent syringes (Diluent, lysis), sampling and air syringes.
  - Liquid valve manifold assembly and tubing.
- Counting chambers :
  - WBC and RBC counting chambers and hemoglobin measurement.
  - Liquid valve manifold assembly and tubing.
- Optical Manifold :
  - Liquid valve manifold assembly and tubing.
- Optical bench :
  - Optical bench (patented) with its flow cell (patented).



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Mono electronic board

The mono electronic board is located between the hydraulic part and the reagent tray.
The board, driven by a 32-bit processor, manages the following parts:

- Fluidics: sample needle, rocker, syringe block motors.
- Autoloader: loading, transfer, mixing and unloading.
- Display and keyboard.
- Connection mode (RS232, Ethernet …).
- Printer.
- Measurement (Optical and resistive counting, hemoglobin measurement).
- Data processing.
- External barcode reader.

⚠	**To avoid all deterioration risks, only the field service engineer may touch this electronic board.**

2.4.3 Power Supply Block

MYTHIC 22 AL is supplied with an external power supply block.

⚠	**- In case of replacement of the main power wire supplied with the MYTHIC 22 AL, the new one must be in compliance with the local regulations.** **- The MYTHIC 22 AL has been certified with the power supply box provided with the machine. - If another power supply is used with the instrument, Orphee or its representative will not apply any warranty on this power supply and on the instrument. Please contact Orphee or its local representative before using such material.**

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2.4.4 Reagent tray

The reagent tray is dedicated to the OnlyOne lysing reagent and cleaning solution bottles.

2.4.5 Sampler

- This module enables to load, transfer, mix and unload the racks. Ten racks of five tubes can be loaded. The loading can be done continually.
- The rack are loaded on the guide rail by a loading screw then displaced by another screw (transfer screw).
- The rail which maintains the rack can also rotated for mixing the blood inside the tubes.
- When all the samplings are performed for a rack, it is unloaded by the unloading motor.

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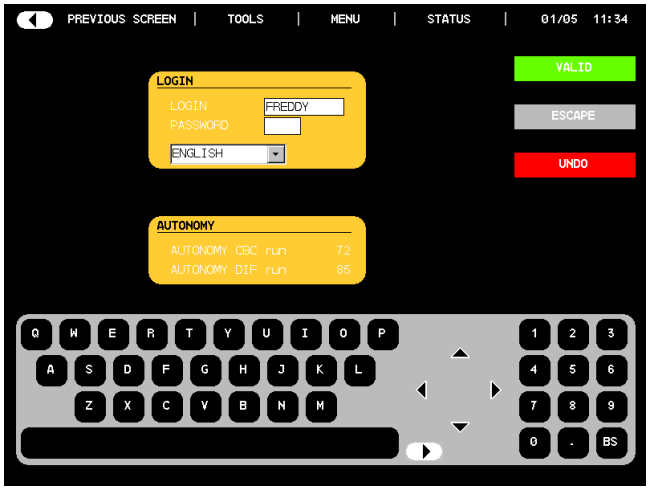
3. INSTRUMENT SET UP

3.1 USER'S IDENTIFICATION

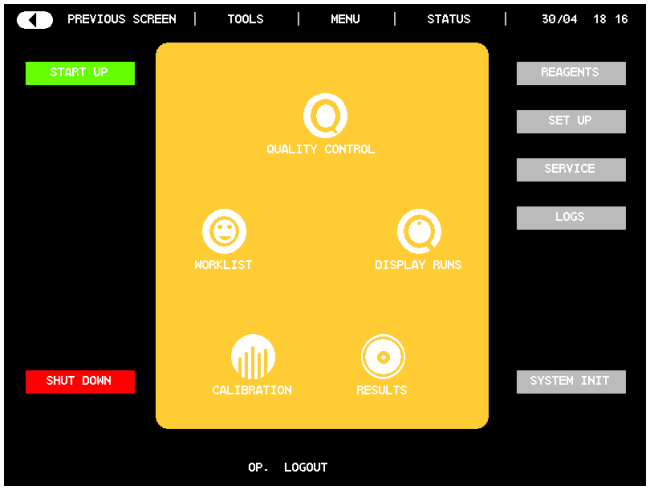
3.1.1 Start Up Machine



- After the instrument's initialization, the identification window is displayed.
- In the window LOGIN FREDDY, the last operator's identification appears.
- Either the identification is yours, press PASSWORD and enter your password or the identification is not, enter your login with the keyboard.
- The window ENGLISH enables to change the language.
- To validate or not the modification, see section 8.7.1.
- **AUTONOMY (run)** indicates the number of samples (runs) you can perform (calculated with the smaller quantity of reagents).

- Enter your identification name with the alphabetic keyboard.
- Place the cursor in the Password window.
- Enter your password for identification.
- For the first login, **MYTHIC 22 AL** proposes 3 access levels:
  - **User** : No password
  - **Biologist** : Password by default **1- 2- 3**
  - **Service people**
- Biologist Password can be modified in section 3.3.6.

3.1.2 In process



- To change operator during the process, press MENU to return to the main menu, and then press on OP. LOGOUT

- To change identification, proceed as described above (section 3.1.1).

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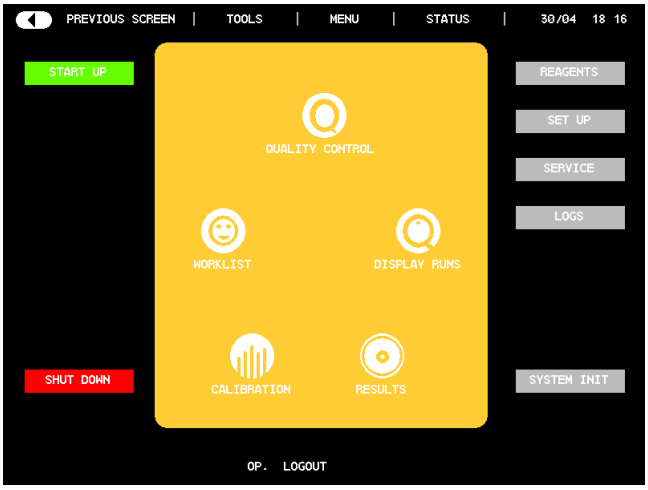
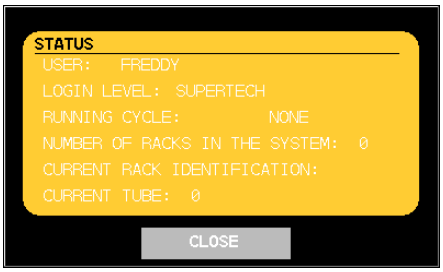
3.2 SYSTEM STATUS



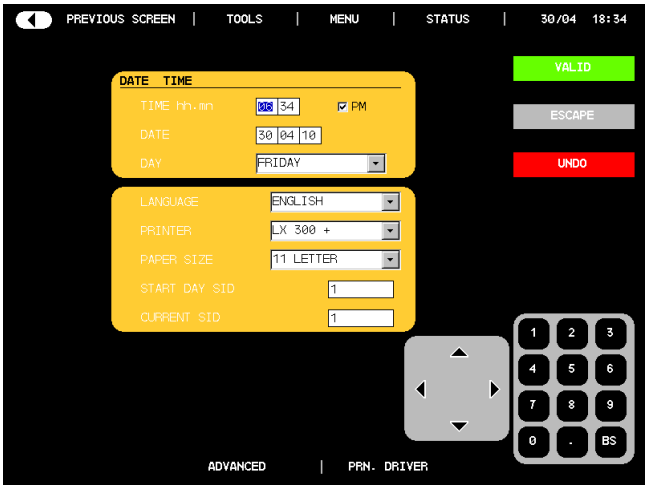
- Press on the date and hour 23/02 10 16 to have access to the system information window.

- Press on STATUS to have access to the status of the **MYTHIC 22 AL**.



- Different information are displayed:
  - Name of the operator
  - Level of access
  - Name of the cycle in progress
  - Number of racks

3.3 SET UP



- From the **MAIN MENU** press on SET UP
- This menu is available for all users.
- The **DATE & TIME** window enables to modify the time, the date and the day.
- To select the language of the Mythic menu, choose the right one in the **LANGUAGE** combo box.
- **PRINTER**: Select the printer or no printing.
- **PAPER SIZE**: Select the paper size per result.
- Two SID are available;

  START DAY SID enables to select the first SID for each new day.

  CURRENT SID enables to fix the beginning of the current SID number (which will be used in the AUTO SID number in the work list, see section 5.6.2)

- ADVANCED : Biologist reserved for complete settings. (See section 3.4).
- To validate or not the modification, see section 8.7.1.

- Press TOOLS to save, load (RESTORE), print or delete all the settings, from an USB key. Three pages are required to print all the settings.

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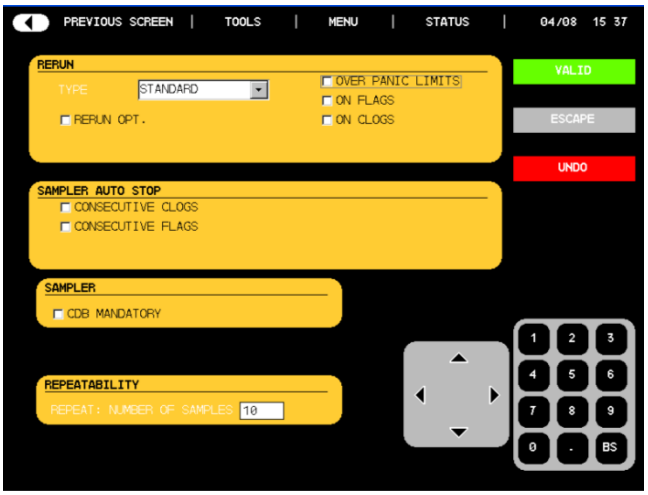
3.4 ADVANCED SET-UP

- **This menu is reserved to biologist** (see section 3.1).

	Any modifications may affect the quality of the results. We recommend to modify these values only after an Orphee's training.

- Please refer below for the description of each key.

3.4.1 Sampler option:



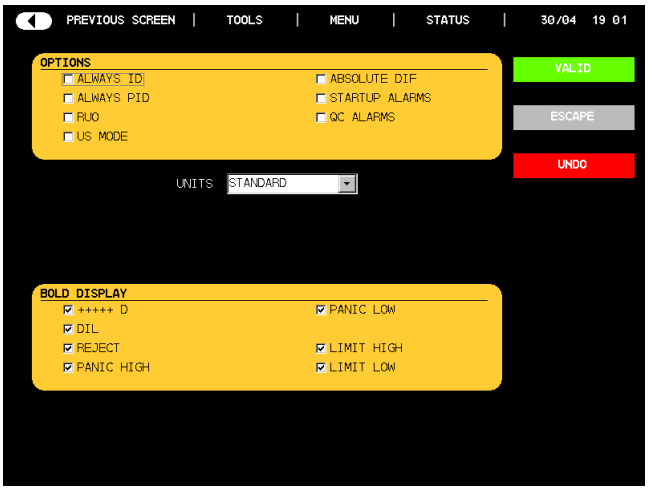
RERUN: For each type of blood you can select the conditions:
- **OVER PANIC LIMITS:** (see section 3.4.6.1)
- **ON FLAGS:** (see section 3.4.6.3)
- **ON CLOGS:** the rerun will be done when one or several parameters are clogged.

SAMPLER AUTO STOP: Conditions of sampler stop:
- After 3 consecutive clogs on the same parameter
- After 3 consecutive flags on the same parameter

SAMPLER: The sampler will draw only the blood with a CDB.
REPEATABILITY: Enter a number to fix the number of sampling done in the repeatability test in RUN RACK mode (see section 6.3)

- To validate or not the modification, see section 8.7.1.

3.4.1 Analysis options:



- **OPTIONS** box:
ALWAYS ID and **ALWAYS PID**: To run a sample, it is mandatory for the user to enter a ID and/or a PID.
RUO: With tag the PCT and PDW parameters are displayed, printed and sent.
US MODE: The Research Use Only message is printed under the printing report.
ABSOLUTE DIFF: With tag absolute values for sub-populations of leucocytes are displayed. In the other case, percentages are displayed.
QC ALARMS: The message "QC failed" appear under the printing report when the QC result is out of tolerance or expired; the message "QC not done" appear under the printing report when it is not run.
- UNITS STANDARD : Gives a choice of three unit systems: Standard, International System, and mmol.

- **BOLD DISPLAY** box: display and print in bold-faced type the different choices in this box.
- To validate or not the modification, see section 8.7.1.

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3.4.2 Lab. parameters:

- Select the blood type in the combo box TYPE STANDARD then press:

LIMITS to adjust the normal and panic limits (see section **3.4.4.1**).

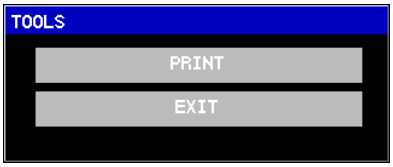
THRESHOLDS to adjust the parameters thresholds (see section **3.4.4.2**).

FLAGS LEVEL to adjust the flags level (see section **3.4.4.3**).

CORRECT. FACTORS to adjust the correction factors (see section **3.4.4.4**). **NOTA**: No correction factors with type STANDARD.

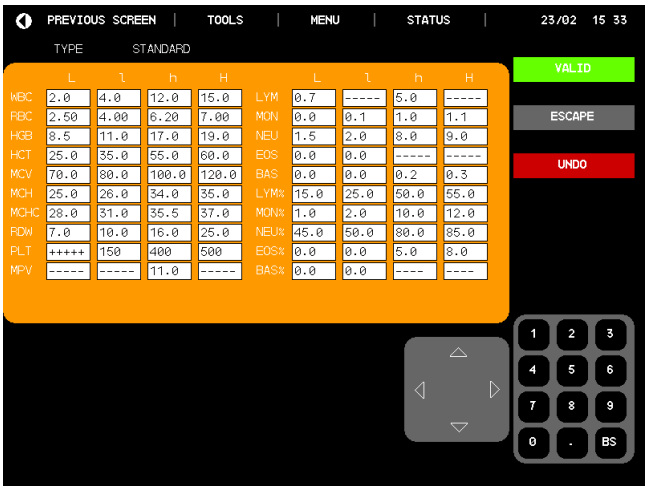
- To enter a new blood type, press RENAME TYPES

NOTA: The name of the first STANDARD type cannot be changed.



- Press TOOLS to print the blood type set up.
- **PRINT** allows to print all the blood type set up (about **20** pages are printed)
- **EXIT** to leave the prompt without action.

3.4.6.1 Limits:



- This display enables to enter normal and panic limits for every 22 parameters performed by the **MYTHIC 22 AL** (see section 8).

- The limits are those of the type displayed above the table.

- To validate or not the modification, see section 8.7.1.

- Press INIT. STD. to return to the parameter setting of the standard type.

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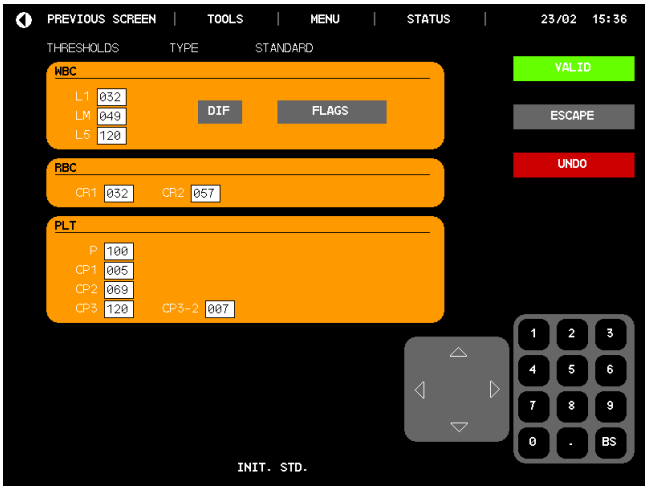
Example of reference values from **LABORATOIRE D'HEMATOLOGIE DU C.H.U. D'ANGERS (FRANCE)**

	First week	8 days to 3 months	3 months to 3 years	3 to 6 years	6 to 15 years	Adult
WBC $10^3/\mu L$ ($10^9/L$)	10,0 to 30,0	6,0 to 18,0	6,0 to 15,0	5,0 to 13,0	5,0 to 11,0	4,0 to 10,0
Neutrophils ($10^3/\mu L$)	6,0 to 26,0	1,5 to 8,5	1,5 to 8,5	1,5 to 8,5	1,8 to 8,0	1,8 to 7,5
Eosinophils ($10^3/\mu L$)	0,2 to 0,85	0,2 to 1,2	0,05 to 0,7	0,02 to 0,65	0 to 0,6	0,04 to 0,8
Basophils ($10^3/\mu L$)	0 to 0,64	0 to 0,2	0 to 0,2	0 to 0,2	0 to 0,2	0 to 0,2
Lymphocytes ($10^3/\mu L$)	2,0 to 11,0	2,0 to 11,0	4,0 to 10,5	2,0 to 8,0	1,5 to 6,5	1,0 to 4,5
Monocytes ($10^3/\mu L$)	0,4 to 3,1	0,05 to 1,1	0 to 0,8	0 to 0,8	0 to 0,8	0,2 to 1,0
RBC $10^6/\mu L$ ($10^{12}/L$)	5,0 to 6,0	3,8 to 4,8	3,6 to 5,2	4,1 to 5,3	4,0 to 5,4	M : 4,5 to 5,8 F : 3,8 to 5,4
HGB g/dL	14,5 to 22,5	10 to 16	10,5 to 13,5	10,5 to 13,5	11,5 to 14,5	H : 13,5 to 17,5 F : 12,5 to 15,5
HCT %	44 to 58	38 to 44	36 to 44	36 to 44	37 to 45	M : 40 to 50 F : 37 to 47
MCV fl	100 to 120	85 to 96	70 to 86	73 to 89	77 to 91	82 to 98
MCH pg	34 to 38	24 to 34	23 to 31	24 to 30	24 to 30	> or = 27
MCHC g/dL	32 to 36	32 to 36	32 to 36	32 to 36	32 to 36	32 to 36
PLT $10^3/\mu L$ ($10^9/L$)	150 to 400	150 to 400	150 to 400	150 to 400	150 to 400	150 to 400

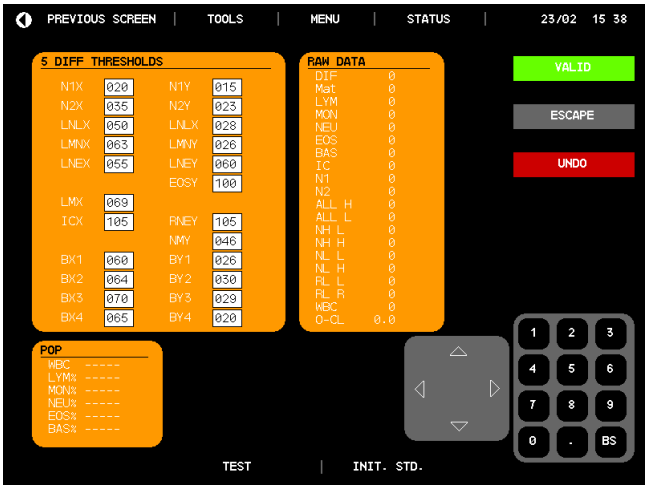
3.4.6.2 Thresholds:



- The threshold display enables to modify the detection thresholds located on the WBC scattergram and RBC, PLT curves (see section 8).

	Threshold modifications may affect the quality of the results or the alarm detection area. We recommend to modify these values only after an Orphee's training.

- Press **INIT. STD.** to return to the manufacturer parameter setting.
- To validate or not the modification, see section 8.7.1.
- To accede to modification of the scattergram threshold press **DIF**.



	Threshold modifications may affect the quality of the results or the alarm detection area. We recommend to modify these values only after an Orphee's training.

- Press **INIT. STD.** to return to the manufacturer's parameter setting.
- Press **TEST** to check the modification on the scattergram of the last run.
- To validate or not the modification, see section 8.7.1.
- To access to modification of the flags threshold press **FLAGS**.

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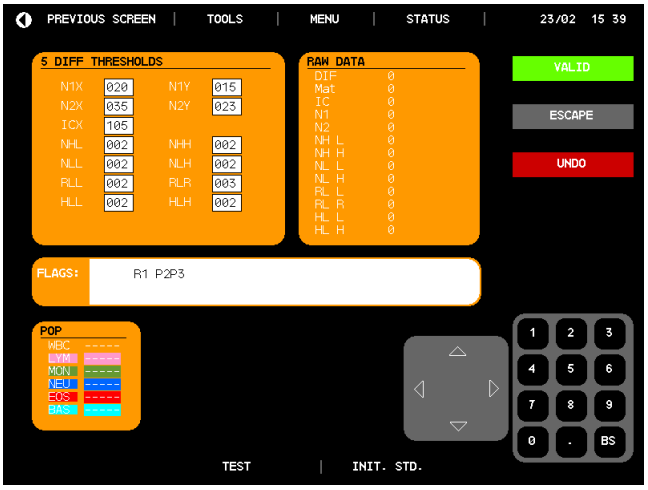


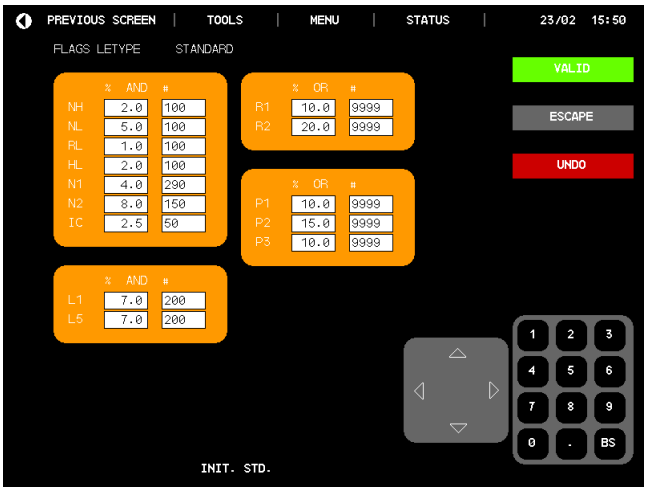
	Threshold modifications may affect the quality of the results or the alarm detection area. We recommend to modify these values only after an Orphee's training.

- Press **INIT. STD.** to return to the manufacturer's parameter setting.

- Press **TEST** to check the modification on the scattergram of the last run.

- To validate or not the modification, see section 8.7.1.

3.4.6.3 Flags level:



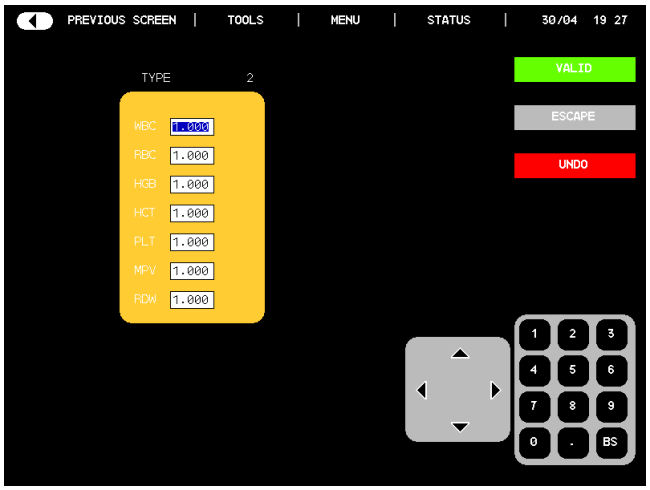
- In the Alarm menu, users can modify the sensitivity of the alarms for the different cells: WBC, RBC, PLT and differential (See section 8.5).

- The WBC flags appear when the % limits **AND** # limit are reached.
- The RBC and PLT flags appear when the % limit **OR** # limit are reached

- To validate or not the modification, see section 8.7.1.

- Press **INIT. STD.** to return to the parameter setting of the standard type.

3.4.6.4 Correction factors:



- In this menu, for each blood type, users can define a correction factor which is multiplied by the calibration factor (see section 3.4.7) given by a normal calibration (see section 7).

- To validate or not the modification, see section 8.7.1.

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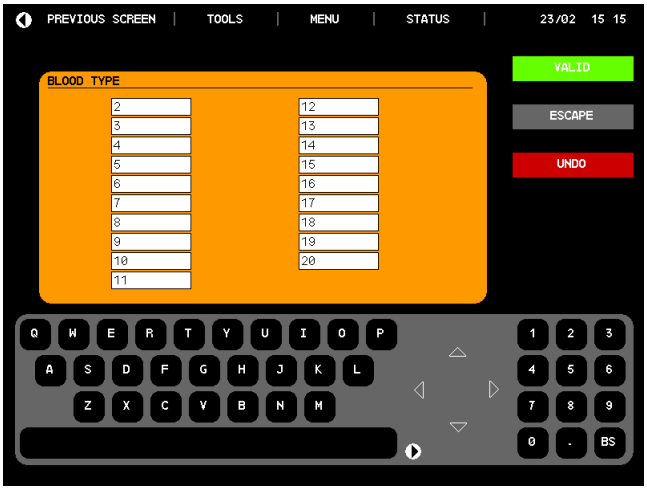
3.4.6.5 Rename types:

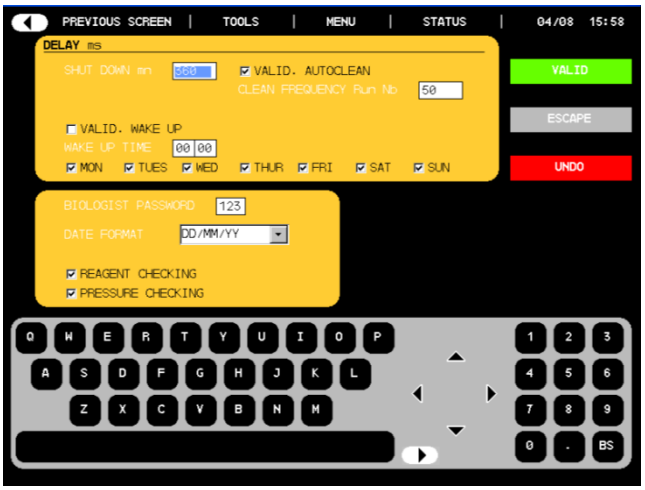


To rename a blood type, press RENAME TYPES then select the box to change and enter the name of the new type with the alphabetic keyboard.

- To validate or not the modification, see section 8.7.1.

NOTA: The name of the first STANDARD type cannot be changed.

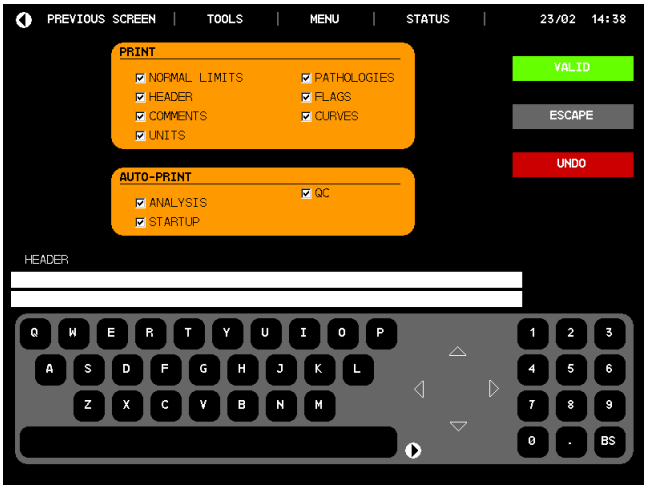
3.4.3 Other Setting:



- In **DELAY** box, the user can modify:
  - Time in minutes to start the automatic shut down.
  - Time in minutes to raise up the needle.
  - The setting of the automatic cleaning: ☑ VALID. AUTOCLEAN and its frequency in number of analysis: CLEAN FREQUENCY Run Nb 80 .
  - The setting of the of the automatic wake up ☑ VALID. WAKE UP and its daily time WAKE UP TIME 00 00 and the day of the week.
- Reagent checking enables the reagent control (see section 1.5.2)
- Pressure Checking is available for technicians only.
- The entry BIOLOGIST PASSWORD 123 enables to modify the biologist password.
- The entry DATE FORMAT DD/MM/YY enables to select the date format.

- To validate or not the modification, see section 8.7.1.

3.4.1 Printer set up:



- Printer set up menu is intended to present the printing report
- To select an option on the report, press on the corresponding case.
- To enter a header, use the keyboard.

- To validate or not the modification, see section 8.7.1.

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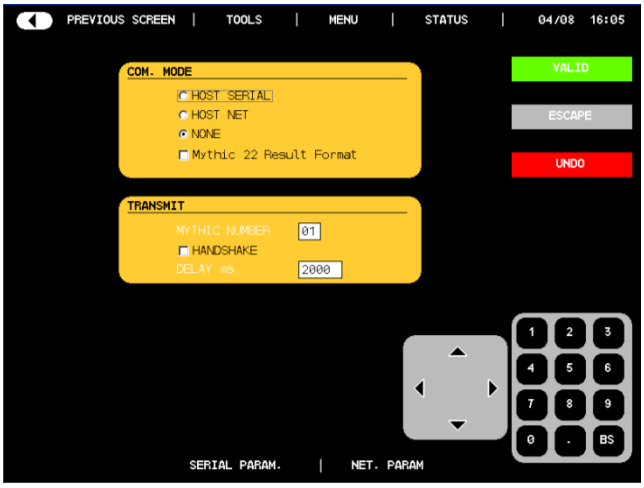
3.4.1 Communication:



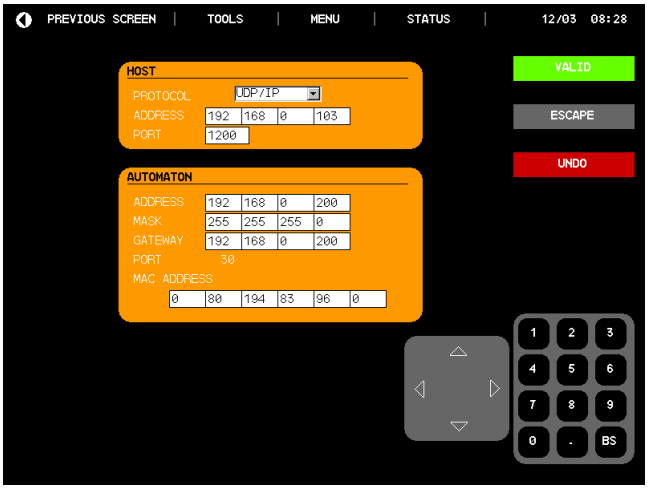
- Reserved for Field Service Engineer.
- To set up the connection between **MYTHIC** and Host.

- To validate or not the modification, see section 8.7.1.

3.4.2.1 Serial Param.

- Reserved for Field Service Engineer.

3.4.2.2 Netware Param.



- Reserved for Field Service Engineer.

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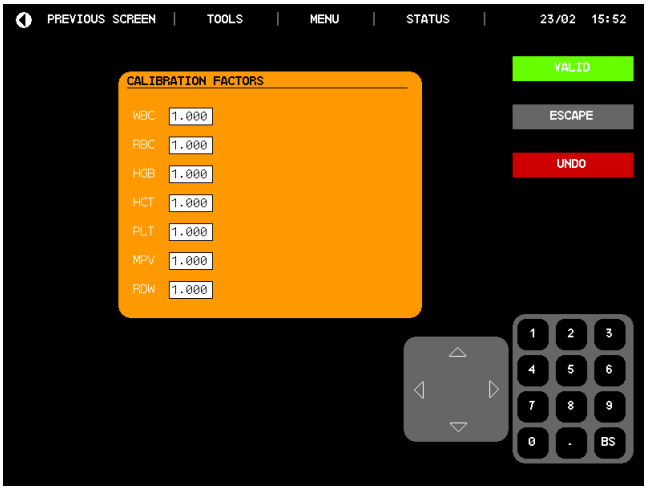
3.4.2 Calibration factor:

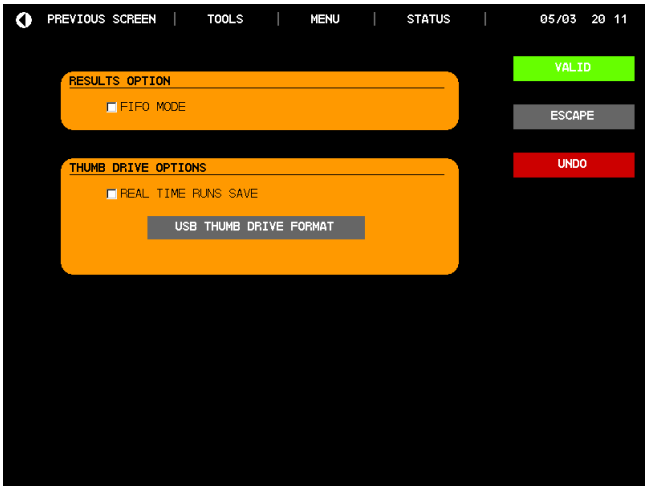


- In this menu, the user can modify the calibration factors without any calibration with calibration blood.
- A **M** letter appears on the right of the date of calibration in case of modification in the Calibration Menu..

⚠	**The modification of any of these factors without running a calibration blood may affect the quality of the result.**

- To validate or not the modification, see section 8.7.1.

3.4.3 Storage options:



MYTHIC 22 AL can save more than the last 1500 patients with results, alarms, distribution curves in the internal memory and up to a maximum of 60 000 results in a memory stick (USB key) with capacity from 128 Mb to 2 Gb maximum. Because the technologies of the USB key are very different some of them may not work. For more information, contact your Orphee representative.

- Choose for a FIFO (first in /first out) mode or real time to store the results in the resident memory or in a USB key.

- To validate or not the modification, see section 8.7.1.

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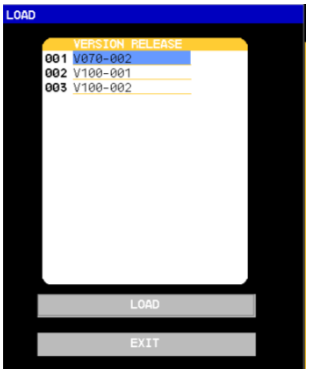
3.4.4 Version release:

⚠	**Load a new software version only with the agreement of an Orphee's representative. Be sure to load the new upgrade in the right folder on the USB thumb drive. If you have any doubt, please contact Orphee S.A. service department or your Orphee's representative.**

- Place the USB key with the new software in the USB connector at the rear of the MYTHIC 22AL.

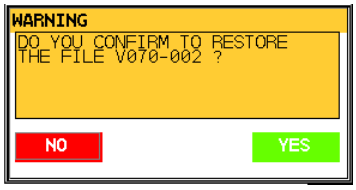
- Press VERSION RELEASE to load the new software version.

- The different prompts hereafter appear to help you during the loading.

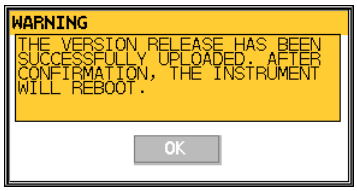


- Select the software version to load and press **LOAD**.

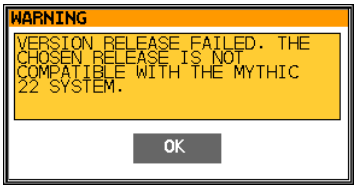
- Press **EXIT** to exit of the prompt without action.



⚠	**The current software version will be definitively erased and replaced by the new one. Press yes only if you are sure you want to load a new version software**



- This prompt appears to confirm the version has been successfully loaded.



- This prompt appears when the release of the software has failed.

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4. SPECIFICATIONS

4.1 ANALYTICAL SPECIFICATIONS

Throughput: Close tube mode: > 40 samples/hour
Other vial mode: > 45 samples/hour

Sampling Volume: 18.2 µl (Nominal volume inside the needle, the total volume could be upper according to the blood remaining outside of the needle).

Measurement Principle: WBC/RBC/PLT: Impedancemetry
Five part diff: Optical flow cytometry
Hemoglobin: Spectrophotometry at 555 nm
Hematocrit: Volume integration

Linearity:
Linearity is measured with linearity sample performed four times for each level.

PARAMETERS	RANGE	LIMITS (the larger)
WBC ($10^3/mm^3$)	0 to 100	+/- 0,4 or +/- 4%
RBC ($10^6/mm^3$)	0,1 to 8	+/- 0,07 or +/- 3%
HGB (g/dL)	1,0 to 24	+/- 0,3 or +/- 2%
HCT (%)	5 to 70	+/- 2 or +/- 3%
PLT ($10^3/mm^3$)	5 to 2 000	+/- 10 or +/- 5%

Reportable range:
Within the reportable range, the results are flagged with a **D** to indicate that it is necessary to re-dilute and re-run the sample.

PARAMETERS	REPORTABLE RANGE
WBC ($10^3/mm^3$)	100 to 150
RBC ($10^6/mm^3$)	8 to 15
HCT (%)	70 to 80
PLT ($10^3/mm^3$)	2000 to 4 000

Repeatability:
Calculated with 20 runs of a fresh whole blood sample performed on a commercial **MYTHIC 22 AL**.

PARAMETERS	CV	RANGE
WBC	< 2,5%	> to $6,0\times10^3/mm^3$
LYM%	< 5%	> to 15 %
MON%	< 10%	> to 7 %
NEU%	< 4%	> to 50 %
EOS%	< 10%	> to 5%
BAS%	< 40%	> to 2%
RBC	< 2%	> to $4,0\times10^6/mm^3$
HGB	< 1,5%	> to 12,0 g/dL
HCT	< 2%	> to 40,0 %
MCV	< 1%	> to 85 fL
RDW	< 4%	> to 14
PLT	< 5%	> to $250\times10^3/mm^3$
PMV	< 3%	> to 8 fL

Calculation method:

$$CV = \frac{SD}{\overline{X}} \qquad SD = \sqrt{\frac{\Sigma x^2 - \frac{(\Sigma x)^2}{N}}{N-1}}$$

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Carry-Over:
For each parameter, 3 runs are performed from a high concentration sample followed by 3 runs without sample.

	WBC	RBC	HGB	PLT
High concentration value	$140\times10^3/mm^3$	$8\times10^6/mm^3$	20g/dL	$3000\times10^3/mm^3$
Measured carry-over (%)	0,29	0,13	0	0,07
Maximum carry-over (%)	< 1,0	< 1,0	< 1,0	< 1,0

The percentages of carry-over inter samples is calculated with the following formula:

$$\text{Carry-over} = \frac{\text{(Low value cycle 1) - (Low value cycle 3)}}{\text{(High value cycle 3) - (Low value cycle 3)}} \times 100$$

Accuracy:
Results of the correlation done with one commercial instrument (SYSMEX XE 5000® for the MYTHIC 22 AL and HORIBA ABX PENTRA 120® for the MYTHIC 22) and with normal blood samples (without alarm).

	MYTHIC 22 vs PENTRA 120		MYTHIC 22 AL vs SYSMEX XE5000	
PARAMETERS	N	R (%)	N	R (%)
WBC ($10^3/mm^3$)	127	0,997	103	0.984
LYM (%)	113	0,989	97	0.935
MON (%)	113	0,935	97	0.896
NEU (%)	113	0,988	97	0.957
EOS (%)	113	0,950	97	0.906
BAS (%)	113	0,187	97	0.253
RBC ($10^6/mm^3$)	127	0,991	103	0.993
HGB (g/dL)	127	0,997	103	0.993
HCT (%)	127	0,984	103	0.984
MCV (fL)	127	0,947	103	0.940
RDW (%)	127	0,746	103	0.836
MCH (pg)	127	0,963	103	0.954
MCHC (g/dL)	127	0,151	103	0.623
PLT ($10^3/mm^3$)	127	0,990	103	0.960
MPV (fL)	127	0,890	103	0.886

Calculation method:

$$\mathbf{r} = \frac{n.\Sigma xy - \Sigma x.\ \Sigma y}{\sqrt{(n.\ \Sigma x^2 - (\Sigma x^2))(n.\ \Sigma y^2 - (\Sigma y^2))}}$$

Mode to mode (closed tube and other vial) acceptable differences:

PARAMETERS	MEAN DIFFERENCE (whichever is greater)
WBC ($10^3/mm^3$)	0,5 or +/- 5%
RBC ($10^6/mm^3$)	0,3 or +/- 2%
HGB (g/dl)	0,5 or +/- 2%
PLT ($10^3/mm^3$)	40 or +/- 7%

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4.2 PHYSICAL SPECIFICATIONS

General:
Ambient temperature: from 18 to 34°C
Relative Humidity: 80% maximum at 31°C
Storage temperature: -10 to 50°C
Altitude up to 3 000 m;

	If the MYTHIC 22 AL has been stored at a temperature lower than 10°C, it should stay at room temperature during 24 hours before being switched on.

INSTRUMENT:

Dimensions:	Height: 410 mm (approx.) Width: 500mm (approx.) Depth: 430 mm (approx.)
Weight:	25 kg (approx.)
Power supply Input:	24V –6,25A DC
Electrical consumption:	During cycle: 60 W (+/-10%) Stand By: 25 W (+/-10%) Maximum: 130 W (+/-10%)
Display:	TFT Color LCD 8.4" (640*480) Mode landscape Retro-lighted
Barcode (optional):	Barcode reader: C39 / Barcode / 2 interleaved 5
Memory capacity:	> 1500 Files (Demographics, results and histograms in the internal memory) > 50 000 results in a memory stick (USB key) of 512 Mbit or more (until 8 Gb) QC: 12 levels (200 Files per level)
Connection:	RS 232C Ethernet (TCP/IP) USB

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Reagent Consumption (ml): Software Version > **V1.0**

CYCLES		DILUENT	LYSE	CLEANER
Run Sample	DIF AL	22.7	1.0	0.6
	CBC AL	14.7	0.8	0.6
	DIF Stat	22.2	1.0	0.6
	CBC Stat	14.4	0.8	0.6
Rinse All		11.0	0.1	0.0
Back flush Aperture		11.2	0.0	0.3
Back flush optics		13.0	0.5	8.2
System Init		14.8	0.0	0.4
Reagent	All	37.8	5.6	4.8
Prime	Lysis OnlyOne	5.7	6.6	0.0
	Diluent	42.0	0.0	0.0
	Cleaner	0.0	0.0	3.4
Cleaning		12.7	0.3	5.5
Bleach		47.8	1.3	0.5
Latex WBC		14.5	1.3	0.5
Latex RBC/PLT		7.2	0.0	0.0
Adj OPT GCAL		13.0	1.0	0.0
Latex OPT		13.1	1.0	0.0
Adjust LED		0.9	0.1	0.0
Start Up *		85.0	3.2	0.6
Shut Down		3.8	0.5	22.0

***** Consumption with one run sample, add one or two run sample DIF consumption if needed.

POWER SUPPLY BLOCK:

Dimensions: Height: 40 mm
Width: 70 mm
Length: 170 mm
Weight: 0,4Kg
Power supply Input: 90 to 260VAC
1A (rms) for 230VAC – 2A (rms) for 115VAC
Power supply output: 24VDC
150W maximum output power

PRINTER (LX-300+)(optional):

Dimensions: Height: 164 mm (approx.)
Width: 366 mm (approx.)
Depth: 275 mm (approx.)
Weight: 4.4 kg (approx.)
Power supply: Model 120V Model 220-240V
99 to 132Vac 198 to 264Vac
50 to 60 Hz
Electrical consumption: 23W (approx.)
Paper size: A4
Printer: Impact (9 needles)
Speed: Up to 300 cps (character per second)

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4.3 REAGENTS SPECIFICATIONS

All the reagents must be stored at room temperature (18°C to 25°C).

4.3.1 Diluent

ORPHEE code number: **HM22-003-10**
Opening shelf life: 60 days.

Application: The diluent is used to carry out the necessary dilutions for the measurement performed by the **MYTHIC 22 AL**.(see section 8)

Active components: Solid content: 0.9%.

Others components: Buffer.
Preservative.

Description: Clear and odorless aqueous solution.

Storage: At room temperature until the expiry date labeled on the bottle.

Precautions: Mayn cause skin and eyes irritation. Wear a smock, gloves and glasses during manipulation.

First emergency care:

Inhalation: Breathe fresh air; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 minutes.
Skin: not skin irritating.
Ingestion: rinse out mouth; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measure :

Person related safety precautions:	Wear protective equipment; keep unprotected persons away
environmental protection:	Do not allow product to reach sewage system or water bodies
cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

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4.3.2 Lytic reagent "OnlyOne"

ORPHEE code number: **HM22-002-1**
Opening shelf life: 60 days.

Application: Only One Lytic reagent is used as unique leukocyte and hemoglobin reagent to lyse red blood cells, enabling cells subpopulations differentiation and counting and quantitatively determining hemoglobin content of blood samples on **MYTHIC 22 AL**, (see section 8)

Active components:
- alkaline salts and buffering means
- ionic and non-ionic surfactants mix
- Leuko-protective agents
- non toxic Hemoglobin chelate
- Preservatives

Description: A clear pale yellow aqueous solution (with slight characteristic smell) composed of alkaline salts, inorganic buffers, leukoprotective agents, detergents, a non toxic hemoglobin stabilizing chelate, and preservatives

NOTA: This reagent does not contain any cyanide, neither formaldehyde, nor azide.

Storage: At room temperature, until expiry date labeled on the bottle.

Precautions: May cause skin and eyes irritation. Wear a smock, gloves and glasses during manipulation.

First emergency care:

Inhalation: Breathe fresh air; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 minutes.
Skin: Abundantly rinse during 15 minutes; seek for medical advice in case of persisting symptoms
Ingestion: give large amount of water; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measure :

Person related safety precautions:	Wear protective equipment; keep unprotected persons away
environmental protection:	Do not allow product to reach sewage system or water bodies
cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

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4.3.3 Cleaning solution

ORPHEE code number: **HM22-001-1**
Opening shelf life: 60 days.

Application: The cleaning solution is used to carry out the cleaning of the measurement system and hydraulic circuit (see section 8).

Components: Enzyme
Propylene glycol 2.5-10%:
Dangerous component with critical values that require monitoring at the workplace
(CAS 55-57-6; EINECS 200-338-0)
OES long term value: 474mg/m^3 150ppm total
10mg/m^3 particles
Violet dye.

Description: Clear aqueous solution, violet color, with characteristic smell

Storage: At room temperature, until expiry date labeled on the bottle.

Precautions: may cause skin and eyes irritation. Wear on a smock, gloves and glasses during manipulation.

First emergency care:
Inhalation: Breathe fresh air; seek for medical advice in case of persisting symptoms
Eyes: Abundantly rinse opened eye during 15 minutes.
Skin: Abundantly rinse during 15 minutes; seek for medical advice in case of persisting symptoms
Ingestion: give large amount of water; seek for medical advice in case of persisting symptoms.

Accidental release and disposal measures:

Person related safety precautions:	Wear protective equipment; keep unprotected persons away
Environmental protection:	Do not allow product to reach sewage system or water bodies
Cleaning/collecting:	Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, saw dust) Comply with local and/or federal disposal legislation

If any doubt, call an emergency center.

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4.4 ANALYTICAL LIMITATIONS

4.4.1 Recommendations

MAINTENANCE:
Please respect the maintenance procedure and the quality control procedure. Otherwise, results may be affected.

GENERALITIES:
Some abnormal samples may give incorrect results by automated cell counting methods. The following table shows examples of specific specimens that could cause errors.

	Each result for a new patient out of lab linearity limits or with an alarm must be checked with a conventional method or checked with blood smear.

	In the case of use of local blood controls or national hematology survey a difference can be observed on the WBC result. This is done by the measurement techniques used in the MYTHIC 22AL. **See the section 8.2.2.**

4.4.2 Interferences

Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 AL	action
WBC	Cold Agglutinin	(+)	*Cause* : high IgM level may lower RBC and increase MCV *Indication* : ↑MCV, ↓HCT, N1 &/or N2 &/or L1 &/or HL flags	Seek for red cell clumping on Smear
	Nucleated RBC Erythroblastosis	(+)	*Indication* : NRBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for NRBC on smear.
	Unlysed RBC	(+)	*Cause*: in some rare instance few erythrocytes may not be completely lysed. *Indication* : lyse-resistant RBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags	
	Cryoglobulins	(+)	*Cause*: In association with various pathologies cryoglobulins cause the WBC, RBC, Plt and Hgb to increase *Indication*: high level of all above mentioned items in case of myeloma, carcinoma, leukemia and other proliferative disorders, pregnancy…	Warm the specimen up to 37°C(99°F) for 30min and re-assay immediately after.
	Platelet aggregation	(+)	*Indication* : aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for Platelet aggregates on smear

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or a decrease in the result which is sample dependent.

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Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 AL	action
LYM (# & %)	Nucleated RBC Erythroblastosis	(+)	*Indication:* NRBC may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags	Seek for NRBC on smear.
	Platelet aggregation	(+)	*Indication:* aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 flags	Seek for Platelet aggregates on smear
MON (# & %)	Large or atypical lymphocytes	(+)	*Cause:* These lymphocytes are larger than normal lymphocytes and tend to overlap the MON clump on the scattergram *Indication:* reduced LYM/MON gap with LYM band RL flags	Seek for Erythroblasts on smear
	Small Neutrophils	(+)	*Cause :* These few segmented and granulations-lacking Neutrophils tend to overlap the MON clump on the scattergram *Indication:* reduced NEU/MON gap with NL flags	
	Lymphoid & myeloid Blasts	(+)	*Cause :* Blasts are large and polymorphic immature cells that may overlap all normal cells clumps *Indication*: reduced/absent LYM/MON even MON/NEU/LYM gap with overlapping population RL &/or NL &/or HL flags	Seek for blasts on smear
	Excessive number of basophils	(+)	*Cause:* in case of basophilia the basophils clump may overlap the MON clump on the scattergram *Indication:* reduced LYM/MON gap RL &/or HL &/or NL flags	Seek for basophils on smear
	Immature monocytes	(+)	*Cause:* Immature monocytic line cells proliferate in certain pathologies (multiple myeloma, monocytic leukemia…) and generate a band at the right of normal MON clump that causes an inaccurate high level of monocytes. *Indication*: : diffuse MON clump with right-end flame population IC &/or L5 &/or NL flags	Seek for immature monocytes on smear
NEU (# & %)	Excessive number of eosinophils	(+)	*Cause:* The excessive presence of eosinophils (eosinophilia) may interfere with NEU counting *Indication:* EOS clump is overlapping NEU clump NH flag	check the eosinophils clump on the scattergram to eliminate eosinophilia
	Immature granulocytes	(+)	*Cause :* metamyelocytes, myelocytes, promyelocytes, blasts or plasma cells are large and polymorphous cells that may overlap NEU clump *Indication:* diffuse spreading out NEU clump NL &/or RL &/or IC &/or L5 flags	Seek for immature cells on smear

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or a decrease in the result which is sample dependent.

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Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 AL	action
EOS (# & %)	Granulations modifications	(-)	*Cause:* Toxic or abnormal granules, as much as degranulated areas may alter optical properties of eosinophils and cause an erroneous EOS counting *Indication:* diffuse downwards spreading EOS clump overlapping NEU clump, NH Flag	Seek for Granulations modifications on smear
	Atypical Neutrophils	(+)	*Cause:* hyper-segmented or giant Neutrophils may overlap EOS clump *Indication:* upwards spreading NEU clump overlapping EOS clump, NH &/or IC &/or L5 Flags	Seek atypical Neutrophils on smear
BAS (# & %)	Blasts, immature, atypical cells	(+)	*Cause:* abnormal cells may overlap the basophils clump and interfere with the basophil counting *Indication:* absence of LYM/MON(NEU) gap with RL &/or NL &/or HL flags	Seek for blasts on smear
RBC	Cold Agglutinin	(-)	*Cause:* high IgM level may lower RBC and increase MCV *Indication:* ↑MCV, ↓HCT	Seek for red cell clumping on Smear
	Severe Microcytosis	(-)	*Cause:* in very rare case of severe microcytosis, size of microcytes may fall under the minimum RBC threshold. *Indication:* ↓RBC, ↑Plt R1 &/or P3 flags	Seek for microcytes on Smear
	Macrocytosis	(-)	*Cause :* in case of macrocytosis, size of macrocytes may overcome the maximum RBC counting zone. *Indication :* ↓RBC, ↑MCV, R2 flag	
	RBC agglutination	(?)	*Cause:* agglutinated RBC may cause a low inaccurate RBC count. *Indication*: abnormal MCH and MCHC values	Seek for clumped RBC on Smear
	Fragmented RBC	(-)	*Cause:* RBC fragments (schizocytes) may agglutinate and interfere with RBC counting. *Indication:* ↓RBC, ↑Plt, ↑MPV, P2 flag	Seek for schizocytes on Smear
	Leukocytosis	(+)	*Cause:* high level of WBC may cause an erroneous RBC count. *Indication:* very high WBC (>100,000/µL), ↑RBC , ↑MCHC	Centrifuge the sample and re-assay the re-diluted RBC part.

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or a decrease in the result which is sample dependent.

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Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 AL	action
HGB	Leukocytosis	(+)	*Cause:* high level of WBC causes excessive light scatter that interferes with Hgb measurement. *Indication:* very high WBC (>100,000/µL), ↑MCHC	Centrifuge the sample remove WBC and re-assay the re-diluted RBC part. Or use reference spectrophotometric method
	hyperlipidemia	(+)	*Cause:* in case of high level of lipids in blood will give the plasma a "milky" appearance that causes inaccurate Hgb measurement. *Indication:* plasma appearance ↑MCHC,	Use reference manual methods and a plasma blank to determine Hgb
	Abnormal Protein hyperproteinemia, hyperbilirubinemia	(+)	*Cause:* in case of high level (or abnormal) of proteins in blood will give the lysed sample a "cloudy" appearance that causes inaccurate Hgb measurement. *Indication:* lysed sample appearance ↑MCHC	Use reference manual methods and a plasma blank to determine Hgb
HCT	Cold Agglutinin	(-)	*Cause:* high IgM level may lower RBC and increase MCV *Indication:* ↑MCV, ↓HCT,	Seek for red cell clumping on Smear
	Leukocytosis	(+)	Elevation of WBC	
	Abnormal Red Cell Fragility	(-)	*Cause*: in case of chemotherapy cytotoxic and immunosuppressive drugs may increase RBC as well as WBC fragility leading to a low HCT *Indication:* P1 flag	
	Spherocytosis	(?)	*Cause:* in case of Spherocytosis, sphered RBC are smaller than normal RBC leading to a low HCT *Indication:* ↓MCV, P2 &/or P3&/or R1 flags	Seek for spherocytes on Smear
MCV	RBC agglutination	(?)	*Cause:* agglutinated RBC may cause an inaccurate MCV value. *Indication*: abnormal MCH and MCHC values	Seek for clumped RBC on Smear Use reference manual methods to determine the accurate MCV value.
	Megalocytic Platelets	(-)	*Cause:* may cause a low inaccurate MCV value because of an excessive size *Indication:* ↓Plt ↑MPV , P2 flag	Seek for megalocytic platelets on Smear
	Leukocytosis	(+)	*Cause:* high level of WBC interferes with MCV determination. *Indication:* very high WBC (>100,000/µL) , ↑MCHC	Use reference manual methods to determine the accurate MCV value.

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or a decrease in the result which is sample dependent.

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Parameter	Specimen		Occurrence Possible Indication of Error on MYTHIC 22 AL	action
MCH	See Hgb value and RBC count interferences		*The MCH is determined according to Hgb value and RBC count. The limitations listed for Hgb and RBC may cause indirect interferences.*	
MCHC	See Hgb and HCT values interferences		*The MCMH is determined according to Hgb and HCT values. The limitations listed for Hgb and HCT may cause indirect interferences.*	
RDW	See RBC count interferences	(?)	*The RDW is determined according to RBC count. The limitations listed for RBC may cause indirect interferences.*	
PLT	Platelet Aggregation	(-)	*Cause:* Clumped platelets may cause a decreased platelet count *Indication:* aggregates may be detected on the WBC scattergram with N1 &/or N2 &/or L1 &/or HL flags, ↓Plt ↑MPV	Seek for Platelet aggregates on Smear The specimen should be recollected in sodium citrate anticoagulant and re-assayed
	Severe Microcytosis	(+)	*Cause:* in case of severe microcytosis, microcytes and schizocytes are under the RBC inferior threshold and may be counted with Platelets and cause an erroneously high Plt count *Indication:* ↓RBC, ↑Plt R1 &/or P3 &/or P2 flags	Seek for microcytes on Smear
	Megalocytic Platelets	(-)	*Cause :* may cause a low inaccurate platelet count as these platelets exceed the upper threshold for the platelet parameter and are not counted *Indication :* ↓Plt ↑MPV P2 flag	Seek for megalocytic platelets on Smear
	RBC agglutination	(?)	*Cause:* agglutinated RBC may trap platelets and cause a low inaccurate Plt count. *Indication:* abnormal MCH and MCHC values	Seek for clumped RBC on Smear
	Hemolysis	(+)	*Cause:* hemolysed samples contain RBC stromas that cause a high inaccurate Plt count. *Indication:* abnormal MCH and MCHC values ↓RBC	

(+): Instrument count is affected by an increase in the result.
(-): Instrument count is affected by a decrease in the result.
(?): Instrument count is affected by either an increase or a decrease in the result which is sample dependent.

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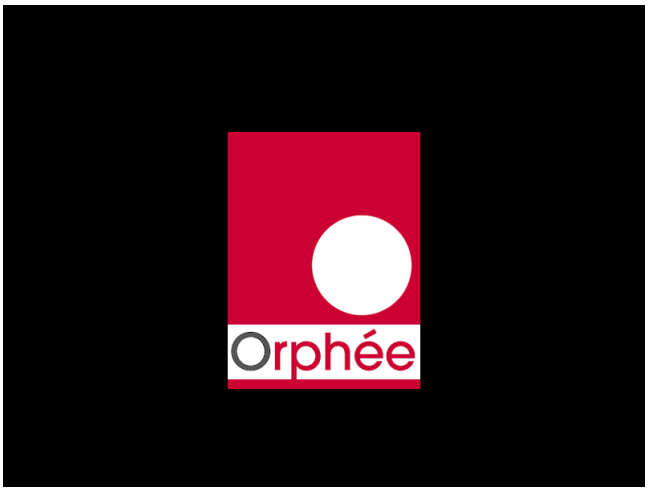
5. SAMPLE ANALYSIS

5.1 VERIFICATIONS BEFORE STARTING

Before starting **MYTHIC 22 AL**, we recommend to check the reagent levels in each bottle, and the level of the waste container. Please also check the paper quantity in the printer.

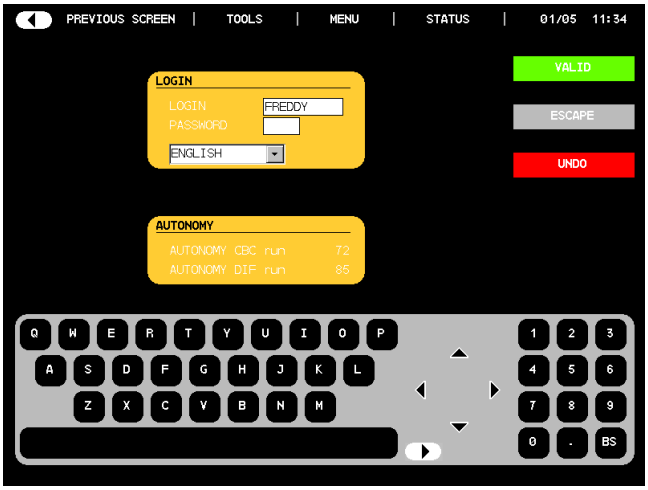
5.2 SWITCH ON

- Press ON/OFF button on the printer to start.
- If needed switch on the power supply (the power supply can stay on).
- Press ON/OFF button on the Mythic.



- The initialization menu is displayed and **MYTHIC 22 AL** performs a home position checking for the three motors of the fluidics and the four motors of the auto loader.

- If one or two racks are always inside the rail, they are transferred to be unloaded.

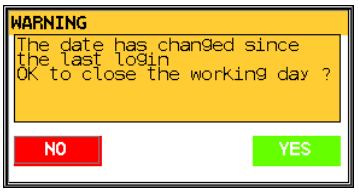


- Enter your login and password as described in section 3.1.

- **AUTONOMY (run)** indicates the number of samples (runs) you can perform in CBC or DIF mode (calculated with the smaller quantity of reagents).

- To validate or not the modification, see section 8.7.1.

- The following prompt appears when you switch on the instrument every day.



	If you press YES the work list will be automatically cleared and the AUTOSID will be reset.

5.3 REAGENT REPLACEMENT

	The reagents must be stored 24 hours minimum at room temperature before use.

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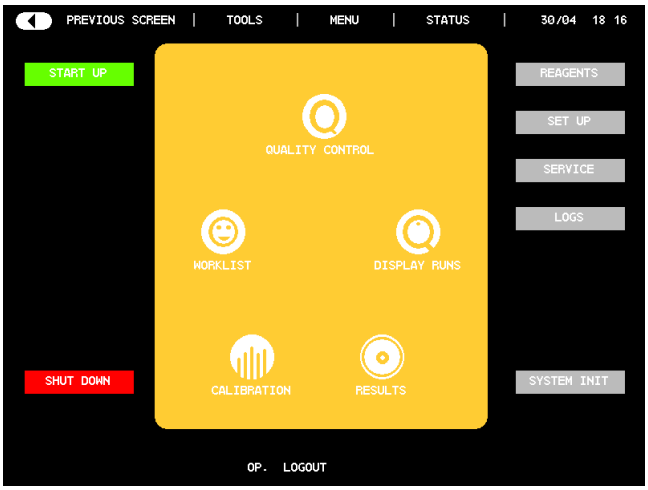
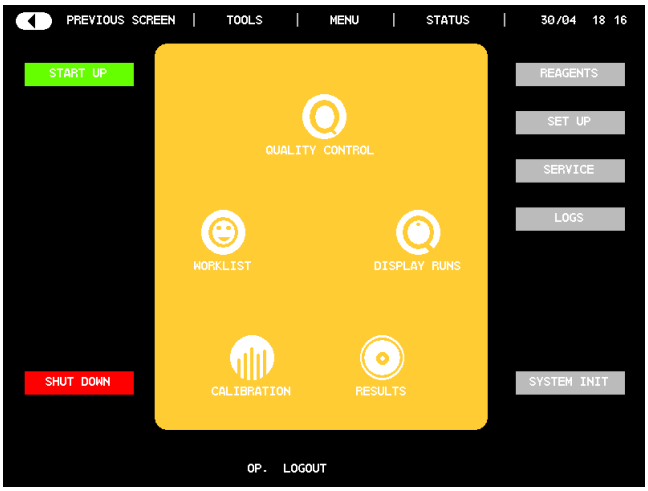


- To check the level of each reagent, press REAGENTS

- If one reagent or more needs to be replaced, proceed as indicated in section 1.5.2

- **AUTONOMY (run)** indicates the number of samples (runs) you can perform in CBC or DIF mode (calculated with the smaller quantity of reagents).

5.4 START UP RINSING



- To rinse the system before analysis, press START UP.
- Mythic will perform 1 to 3 blank cycles to check the carry over level. The level should not to exceed the following:
  - WBC : 0.5
  - RBC : 0.1
  - HGB : 0.5
  - PLT : 10
- If the level is higher, **MYTHIC 22 AL** displays a window "START UP FAILED" press OK and perform a new start up otherwise every result will be printed with **"Start Up not done"** message.
- An automatic Start Up can be performed at a scheduled time (see section 3.4.8)

NOTA	The startup can start as soon as the working temperature is reached (about 20 min at 23°C room temperature).			
	WARNING HEATING IN PROGRESS, PLEASE WAIT. OK	This prompt means that the temperature setting of the enclosure and/or the reagent is not reached yet	INFORMATION SET TEMPERATURE REACHED. OK	This prompt means that the temperature setting of the enclosure and/or the reagent is reached

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5.5 PREPARATIONS BEFORE ANALYSIS

5.5.1 Blood collection

The human blood venous sample must be collected in an EDTA **K2** or **K3** (Ethylene Diamine Tetracetic Acid, two or tri potassic) tube in sufficient quantity. The CBC and 5 part diff results are available up to **48 hours** after the blood draw and if the sample is stored early at 4 to 8°C (more flags may occur).
The results and/or the number of flags may be affected in case of too much sampling in the same tube, around 20 times in function of the type of blood (an aged and/or abnormal blood can be altered before 20 samplings).

	A volume of insufficient blood for the quantity of anticoagulant may involve an erroneous result.

5.5.2 Blood sample collection tube

The following table shows the type of sample collection tubes available with the MYTHIC 22 AL.

	The use of another type of sample collection tube may destroy the sampling needle or give false results, please contact your Orphee's representative before using this different type.

The more important close tube characteristics are the length and diameter for the tube holder, the cap which contains the rubber membrane for the piercing module.
The close tubes serial numbers below are showed only as examples, please contact your tube vendor for more details about EDTA and VACCUM contain.
The minimum volume of blood required in the sample tube is **300µl**.

	BD VACUTAINER	368861	13x75
	BD VACUTAINER	368452	13x75
	BD VACUTAINER	367651	13x75
	BD VACUTAINER	367652	13x75
	TERUMO VENOSAFE	VF054SDK	13x75
	GBO VACUETTE	454034	13x75
	GBO VACUETTE	454024	13x75
	GBO VACUETTE	454087	13x75
	GBO VACUETTE	454023	13X75
	GBO VACUETTE	454036	13x75

		The SARSTEDT tube request a special optional rack (type 02, see section 5.6.6.1), please contact your Orphee's representative for its supply.

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5.6 ANALYSIS

5.6.1 Introduction

⚠	**All the maintenance (see section 9.1) must be done before running any samples or controls.** **The quality of the results cannot be insured if the maintenance is not done.**

⚠	**It is recommended (or mandatory according to the legislation) to carry out a Quality Control (QC) and possibly a calibration before any analysis (see section 6 & 7).** **Read the analytical limitations (see section 4.4) before running the sample.**

⚠	**The working temperature of the fluidic part must be reached before starting the analysis.** **The average time to reach it is around 20 min at a room temperature > 23 °C.**

If the quality control is not carried out, before beginning the series, it is recommended to perform two analyses on a normal sample the day before to check the results are closed to results obtained the day before.

NOTA: The **MYTHIC 22 AL** is delivered with a standard parameter setting described in section 3.

The samples can be run in two sampling modes:
- Closed tube with the use of the racks (see section 5.6.7).
- STAT with open tube or other vial only (see section 5.6.8).

5.6.2 Working rules

General rules:
The analysis of a sample (in RUN RACK or RUN NEEDLE mode) can be run after all fluidics cycles except the SHUT DOWN after which a START UP is mandatory and DRAIN ALL after which a RINSE ALL is mandatory.

Sampler:
The setting rules of working of the rack system are defined in section 3.4.4 (Sampler Options).
Two modes are possible:
1- Barcode exclusive: this mode allows the maximum security because only the tubes with a barcode label and read by the MYTHIC 22AL are run, no error is possible.
2- Barcode and RAC/POS: If the barcode label is not present or in case of non reading, the sample is run and its result is identified by the RAC/POS.

Security rules:
1- SID is mandatory.
2- SID is unique for a patient in a work list.
3- RACPOS is always unique for the order **T**o do (**T** in the column S **S**tatus).
4- If an order is rerun, it is duplicated in the work list.
5- Nothing can be changed when the run is in **P**rogress (**P** in the column S **S**tatus).
6- When an Order is **D**one (**D** in the column S **S**tatus) only the test and the RACPOS can be changed (for the rerun in rack or needle mode).
7- When a rack is finished, and in case of sample tubes missing in the rack, the orders corresponding become **U**nmatched (**U** in the column S **S**tatus).

Association rules:
1- Once a sample is analyzed the result is associated with its order, if the result cannot be associated, an order with AUTOSID with an incremental number initialized at each beginning of day, is automatically generated, see section 3.3 to set up the number.
2- The results are never matched with in progress (**P**) or unmatched (**U**) order.
3- In case of manual match performed by the operator, the letter **M** will appear on the printout.

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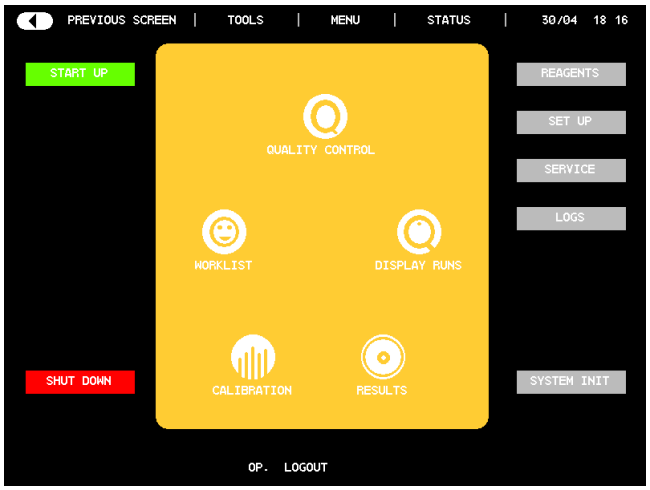
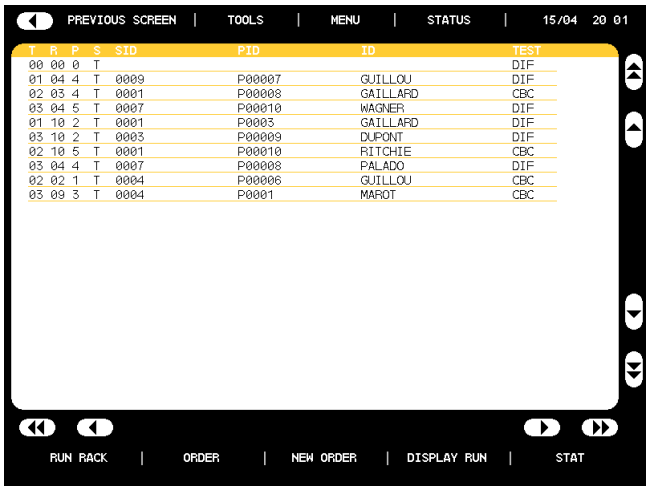
5.6.3 Work list



- Press to access to the work list



- The work list allows to follow the demographic data of each sample to be run.
- The list can be filled out directly from the LIS (see section 3.4.2) or manually.
- To enter the demographic data of a new sample, press NEW ORDER see section 5.6.4
- To modify an existing demographic data, press ORDER (see section 5.6.5)
- To display the full result in progress, press DISPLAY RUN (see section 5.6.6)
- To run an emergency sample (STAT), press STAT (see section 5.6.8).

- Meaning of the columns T R P S:

T is the Type of rack (see section 5.6.7)
R is the number of the Rack (see section 5.6.7)
P is the Position of the tube inside the rack (see section 5.6.7)
S is the Status of the samples: To do (T), Done (D), In Progress (P), done but Unmatched (U).

- Other columns (modifiable in the following sections):

SID : Sample Identification
PID : Patient Identification
ID : Identification
TEST : Type of test requested (CBC or DIF)
GENDER : Male or Female or Unknow
DRAW DATE : Date of the blood drawing
TIME : Time of the blood drawing
DOCTOR : Prescriptor
SERVICE : Origin of the sample
COMMENT : Comments

- Press on TOOLS to delete all, delete the selected order, print or save in internal memory the complete worklist.
- **RESTORE** allows to load a worklist from an USB key and **BACKUP** allows to save the worklist into an USB key

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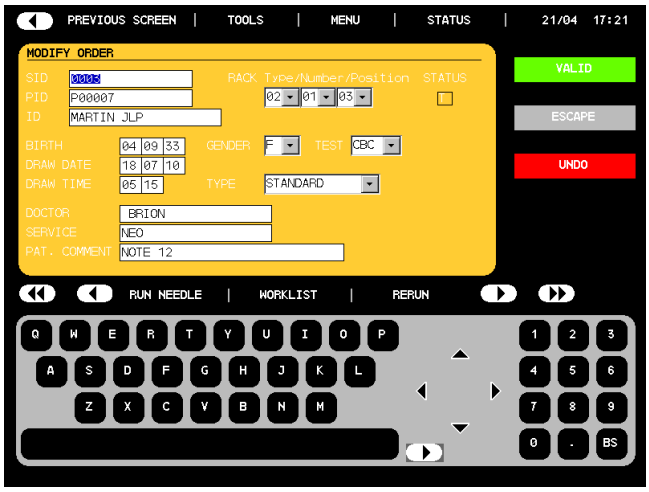
5.6.4 Modify an order

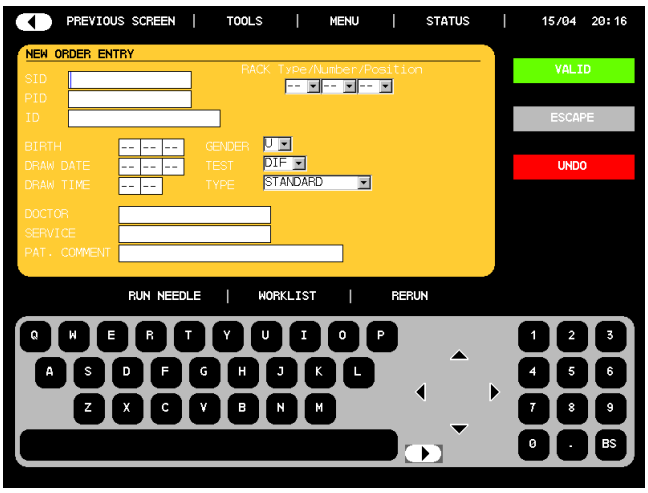


NOTA: A patient order can be modified until the blood is drawn.

- Select the box and enter the modification with the keyboard.
- To validate or not the modification, see section 8.7.1.
- To run this patient in STAT mode or open vial mode press **RUN NEEDLE** (see section 5.6.8).
- To come back to the work list press **WORKLIST** or **PREVIOUS SCREEN**

RERUN is only available when the sample become **D**one (**D**).

5.6.5 New Order



- Enter the demographic data of the new patient with the keyboard.

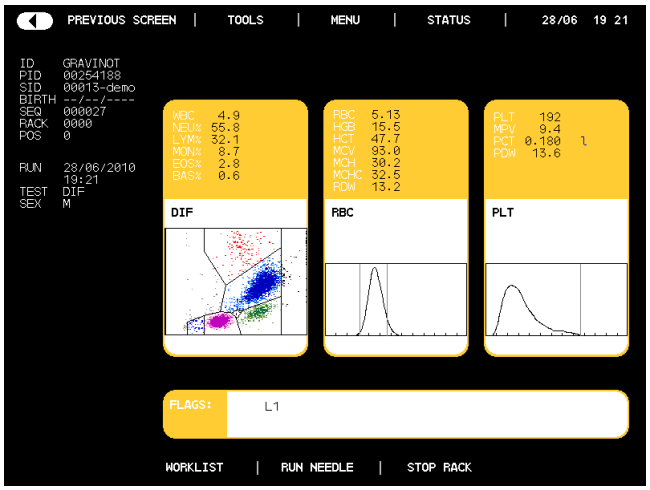
- To validate or not the modification, see section 8.7.1.

- To run this patient in STAT mode or open vial mode press **RUN NEEDLE** (see section 5.6.8).

- To come back to the work list, press **WORKLIST** or **PREVIOUS SCREEN**

RERUN is only available when the sample become **D**one (**D**).

5.6.6 Display run



- This screen allows displaying the last result in progress and its demographic data.
- At each analysis, the screen is updated with the last result.
- To run this patient in STAT mode or open vial mode, press **RUN NEEDLE** (see section 5.6.8).
- To come back to the work list, press **WORKLIST** or **PREVIOUS SCREEN**
- To stop the racks in progress to run a emergency sample or for any other reason, press **STOP RACK**. The movement of the rack stops, then the fluidics stops. To re-launch the rack, press **WORKLIST**, then **RUN RACK**. The analyze re-start at the last sample.

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5.6.7 Run Rack

5.6.7.1 Preparation before loading

	Wear rubber gloves and wash hands with a disinfectant after completion of work.

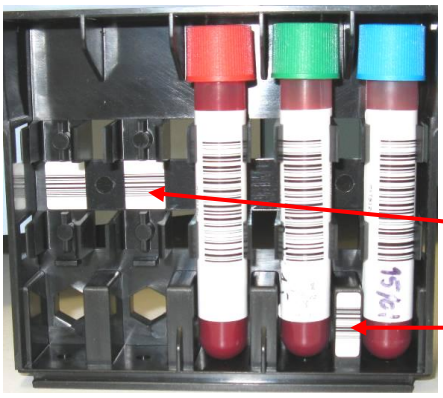
	Never use a rack with a non dedicated sample tube, the needle may be destroyed and the results may be erroneous (See the authorized tubes in section 5.5.2). **If no rack exists for a special vial, please refer to the section 5.6.8 to run it.**

- The label situated at the top of the rack allows identifying the type and the number of the rack.
- The arrow helps the user to introduce the rack in the good position inside the loader.

- In this example, the type is **01** (dedicated for the type of tubes listed in section 5.5.2) and the number of the rack **05**.

- In this example, the type is **02** (dedicated only for the **SARSTEDT** tube) and the rack number **02**

	Before loading the sample tubes in the rack, check if all the caps are perfectly closed.

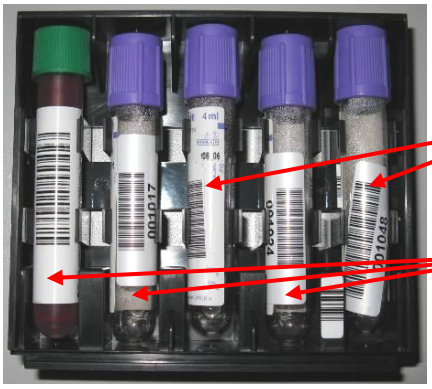


	Before load the rack with the sample tube, check if all the barcode labels are not altered.

- The barcode label of the sample must be placed in front of the rack.

- The barcode labels at the bottom of the rack are used to know if a sample tube is present.

- The barcode label situated between the first two positions is dedicated to identify the type and the number of the rack.



- The barcode label of the sample must be placed in front of the rack.

Bad position of the label.

- **Good** position of the label.

NOTA	If the barcode of the sample cannot be read (bad position, altered, unknown code…) only the rack position (RAC/POS) will appear with the result (see section 5.7). If the barcode of the rack is missing or altered, the rack will be ejected automatically.

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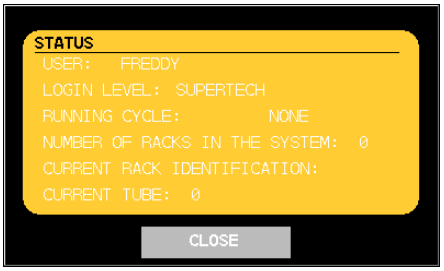
5.6.7.2 Loading and analysis

NOTA	To perform an emergency stop in case of any problem push shortly on the on/off button and see section 9.5.2.

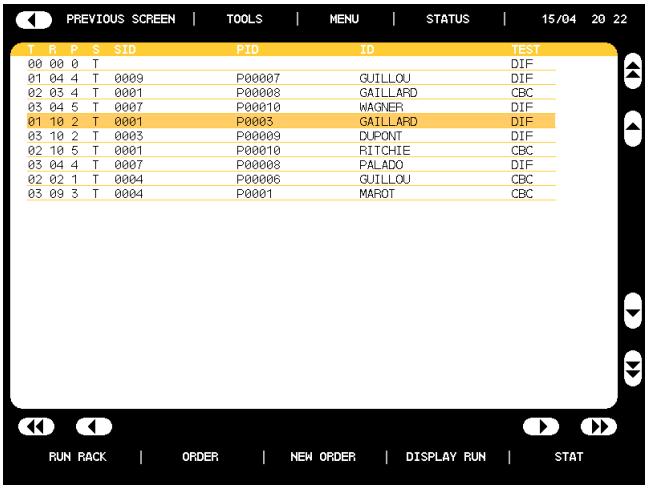


⚠	**Before loading the FIRST rack when the MYTHIC 22AL is operating (the light between the screen and the front door is red), press STATUS located at the top of all screens to see which cycle is in progress and wait for the green light , the other racks may be added at any time on the first one.**

- Place the rack in the right position as shown on the picture.
- The round white label must be placed on the left of the instrument.

NOTA	If the racks are in bad position or not present the auto loader does not start or stop and a prompt appears on the screen to inform the user that no rack is present.

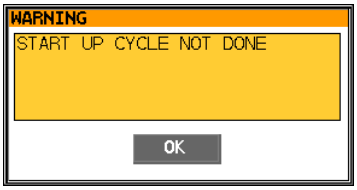
- Introduce a rack or place it in the good position.



- The run of the rack can be launched after having done the demographic entries (see section 5.6.2 and followings).

⚠	**Before launching the sampler you must read all the section 5.6**

- When everything is ready press RUN RACK (read the **NOTA** on the following page).



- This prompt appears if the **STARTUP** has not been done
- Run a **STARTUP** (see section 5.4) otherwise a message "Startup not done" will be printed on all results printings.

- The sampler will work as defined by the user in the Set up (Sampler Options section 3.4.4).

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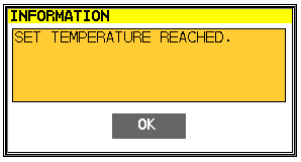
NOTA	To perform an emergency stop in case of any problem, push briefly on the on/off button and see section 9.5.2.

NOTA	The analysis can start as soon as the working temperature is reached (about 20 min at 23°C room temperature).	
	This prompt means that the temperature setting of the enclosure and/or the reagent is not reached yet	 This prompt means that the temperature setting of the enclosure and/or the reagent is reached

5.6.7.3 Unloading

- The racks are unloaded from the sampler automatically.

NOTA	Never breach the exit of a rack, otherwise the sampler will stop in emergency. See section 9.5.2 to restart the sampler.

- The rack can be re-used to load new samples.

To remove each sample, put the rack on the table and push on the bottom of the tube, then take it by the cap.

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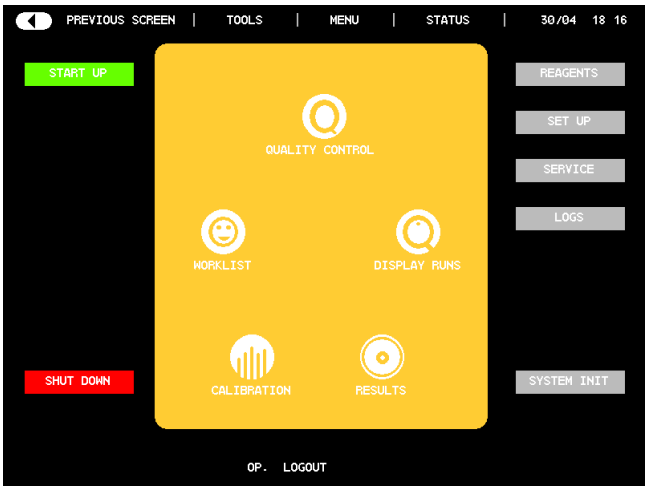
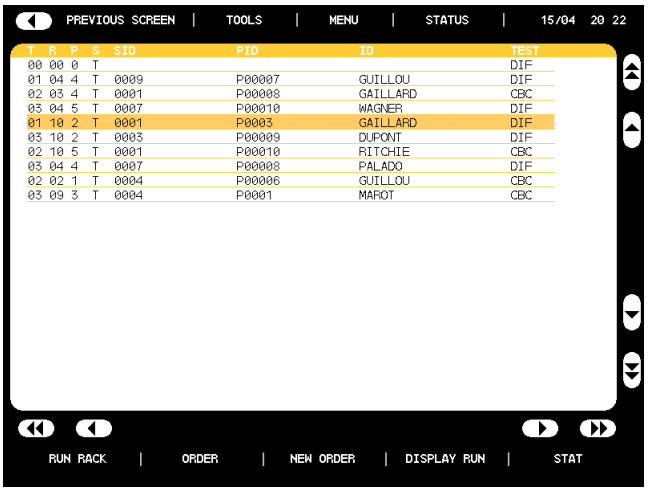
5.6.8 STAT or other vial Sample Identification



- From the main menu, press

to reach the work list table.

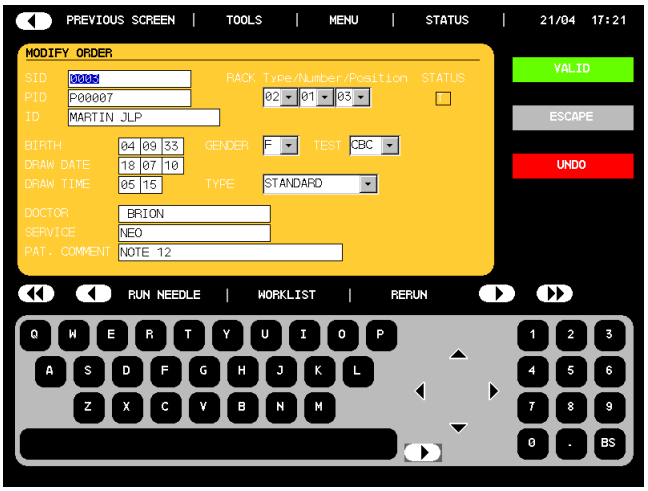


- From the work list, select the demographic data of the sample to be run (the line becomes orange) or:

- To enter the demographic data of a new sample press **NEW ORDER**
- To modify an existing demographic data, select the line then press **ORDER**

- The setting of the work list can be modified in the Set up (see section 3.4.5 Work list Options).

- To run the sample in **STAT** mode or Open vial read hereafter, press **STAT**



- Select the box and enter the modification with the help of the keyboard.

- To validate the modification or not, see section 8.7.1.

- To run this patient in STAT mode or open vial mode, press **RUN NEEDLE**.

- To come back to the work list, press **WORKLIST** or **PREVIOUS SCREEN**

RERUN is only available when the sample become **Done** (**D**).

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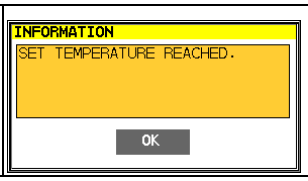
5.6.9 STAT or other vial sample run

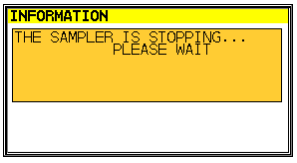
	Wear rubber gloves and wash hands with a disinfectant after completion of work.

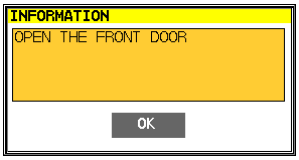
	Behind the front door you will find hazardous moving parts, beware to stay away from these parts if they move when the front door is open and the machine switched on.

NOTA	The analysis can start as soon as the working temperature is reached (about 20 min at 23°C room temperature).			
		This prompt means that the temperature setting of the enclosure and/or the reagent is not reached yet		This prompt means that the temperature setting of the enclosure and/or the reagent is reached

- Before launching the run, enter the identification of the sample (see section 5.6.8)

- Press **RUN NEEDLE** on the display of the **WORKLIST** screen, this prompt appears:



- If the sampler is running, wait for the complete stop, the red light located between the screen and the front door becomes green and a prompt appears on the  screen:

	Never open the door before the complete stop of the sampler, otherwise see section 9.5.2

- Open the front door by pushing on the mark
- The door goes down slowly.

	Be careful with laser light of the barcode reader, if the red light is present during the opening of the door, close it, switch off the AL and call Orphee representative. The barcode reader is a laser CLASS II, never dismantles the cover; in case of problem call Orphee's representative.

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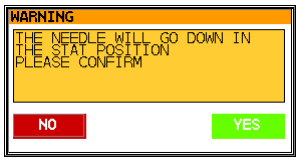
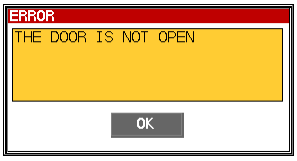
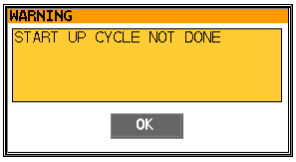


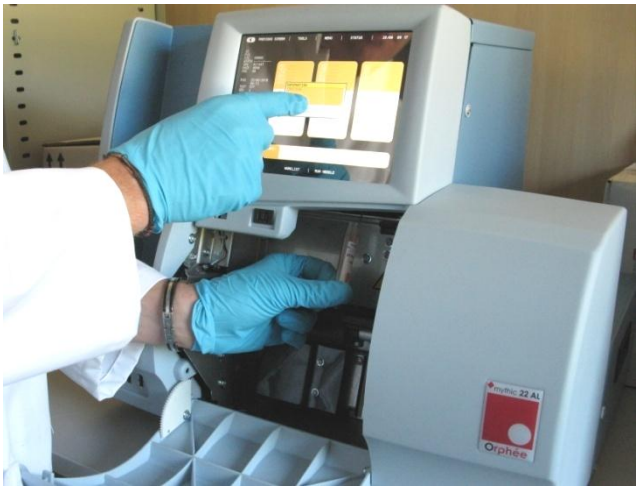
- Press **YES** in the prompt to allow the needle go down.



- Open the door if this prompt appears.

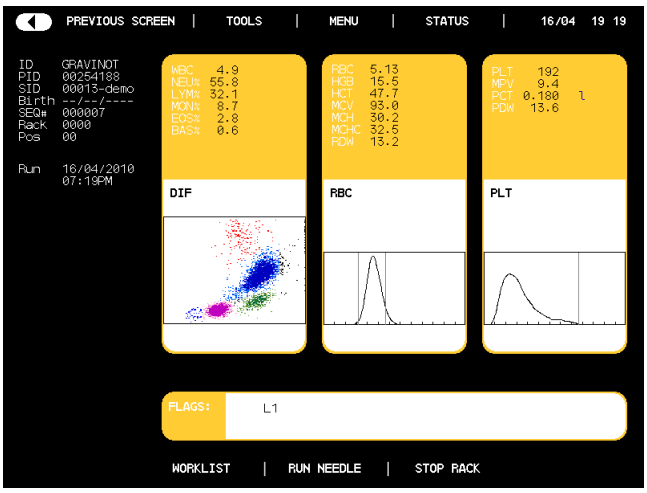


- This prompt appear if the **STARTUP** has not been done
- Run a **STARTUP** (see section 5.4) otherwise a message "Startup not done" will be printed on all results print.



- Introduce the tube of the blood sample without cap under the needle.
- Press **YES** in the new prompt to launch the analysis cycle.
- The green LED becomes red the tube can be removed only when the needle is up.
- A new cycle can be started again when it becomes again green (return to section 5.6.7 to identity the sample).
- As soon as the cycle is launched, the SID is automatically incremented and, thanks to its data processing multitasks; the **MYTHIC 22 AL** is available for the identification of the following sample (See section 5.6.7).
- After running the samples, close the door by pushing the top of the door.

5.7 DISPLAY RUNS



- The results of the analysis are sent before the cycle is finished (to be checked) at the same time as the printer starts.

> **NOTA**: It is not necessary to wait for the end of the result printout to launch a new analysis.

- The results are sent to the selected unit (See section 3).
- The information located on the right of each parameter corresponds to the indicators for out of range limits and for the rejections (see section 3).
- The scattergram and curves of distribution of each cellular population are located on the right screen.
- Under the results, a zone (**FLAGS**) is reserved for analytical alarms (see section 8.5).). Press in this zone to have a clear explanation of the flags.
- At the bottom of the screen, **WORKLIST** allows coming back to the Work list screen and **RUN NEEDLE** allows launching a run in Open Vial mode (See section 5.6.9).

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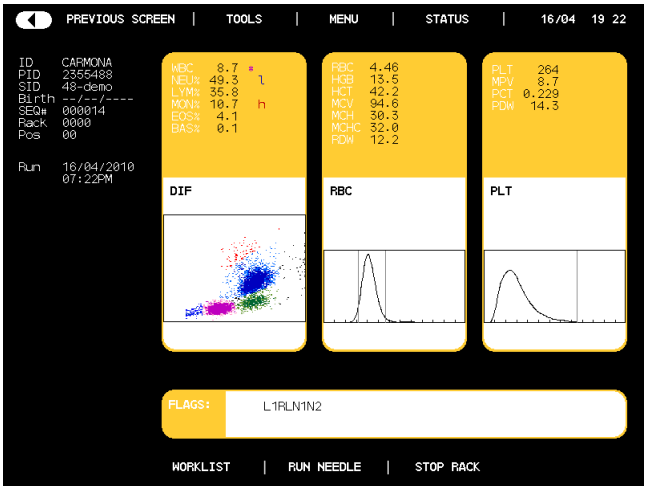
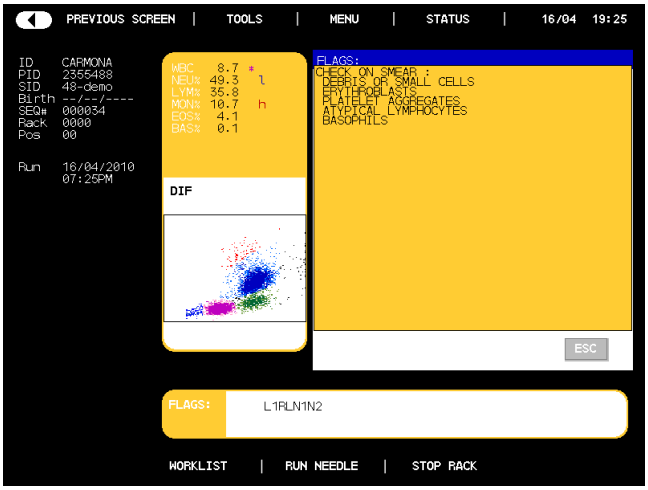


- Example of an abnormal result analysis in **DIF** mode with flags located at the right of the results and in the flag box under the result.

	It is mandatory to read the section 8.5 to understand the flags' meaning.

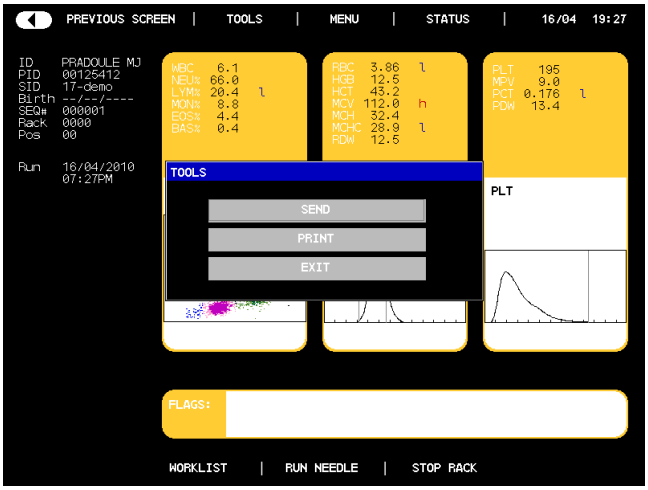


- Press on the flags' zone to open the flags' window.

- With regards to the different flags found by the **MYTHIC 22 AL** the upper part proposes a list of the cells to be checked on the smear.

	In no case, this proposal is a commitment, it is mandatory to read the section 8.5 to understand the flags' meaning.

- The lower part describes the machine trouble (see section 8.5.2).



- Press **TOOLS** to reprint or to resend the result.

- To print the result press **PRINT**.
- To send the result, press **SEND**.
- To close the window, press **EXIT**.

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5.8 PRINTING

Once the analysis is finished, the **MYTHIC 22 AL** prints a result report. To modify the printing presentation or to disconnect the printers, see section 3.4.1.
To load a new printer driver, see section 3.3.

5.8.1 PCL3/LX 300 (USB) model report

One result per page

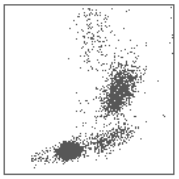
DIF mode

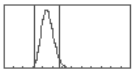
ORPHEE-MEDICAL
Presentation Results MYTHIC 22

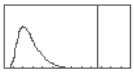
Name :
Comments :
Patient Id :
Sample Id : 00017
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:25:56 Seq# : 00032

	Result	Flags	Unit	Normal limits
WBC	5.7		10^3/l	4.0 / 12.0
LYM%	40.2		%	25.0 / 50.0
MON%	11.3	h	%	2.0 / 10.0
NEU%	42.8	L	%	50.0 / 80.0
EOS%	5.0		%	0.0 / 5.0
BAS%	0.7		%	0.0 / 2.0
LYM	2.3		10^3/l	1.0 / 5.0
MON	0.6		10^3/l	0.1 / 1.0
NEU	2.4		10^3/l	2.0 / 8.0
EOS	0.3		10^6/l	0.0 / 0.4
BAS	0.0		10^6/l	0.0 / 0.2
RBC	5.12		10^6/l	4.00 / 6.20
HGB	15.3		g/dl	11.0 / 17.0
HCT	46.4		%	35.0 / 55.0
MCV	90.6		m^3	80.0 / 100.0
MCH	30.0		pg	26.0 / 34.0
MCHC	33.1		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	308		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.248		%	0.200 / 0.500
PDW	12.0		%	10.0 / 18.0







FLAGS:

MONOCYTOSIS NEUTROPENIA

Comments :

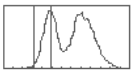
CBC mode

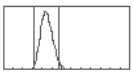
ORPHEE-MEDICAL
Presentation Results MYTHIC 22

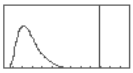
Name :
Comments :
Patient Id :
Sample Id : 00018
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:27:30 Seq# : 00033

	Result	Flags	Unit	Normal limits
WBC	5.8		10^3/l	4.0 / 12.0
RBC	5.14		10^6/l	4.00 / 6.20
HGB	15.4		g/dl	11.0 / 17.0
HCT	46.3		%	35.0 / 55.0
MCV	90.0		m^3	80.0 / 100.0
MCH	29.9		pg	26.0 / 34.0
MCHC	33.2		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	301		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.243		%	0.200 / 0.500
PDW	12.7		%	10.0 / 18.0







FLAGS:

Comments :

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Two results per page

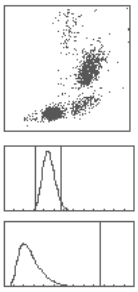
DIF mode

ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00017
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:25:56 Seq# : 00032

	Result	Flags	Unit	Normal limits
WBC	5.7		10^3/l	4.0 / 12.0
LYM%	40.2		%	25.0 / 50.0
MON%	11.3	h	%	2.0 / 10.0
NEU%	42.8	L	%	50.0 / 80.0
EOS%	5.0		%	0.0 / 5.0
BAS%	0.7		%	0.0 / 2.0
RBC	5.12		10^6/l	4.00 / 6.20
HGB	15.3		g/dl	11.0 / 17.0
HCT	46.4		%	35.0 / 55.0
MCV	90.6		m^3	80.0 / 100.0
MCH	30.0		pg	26.0 / 34.0
MCHC	33.1		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	308		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.248		%	0.200 / 0.500
PDW	12.0		%	10.0 / 18.0



FLAGS:

MONOCYTOSIS NEUTROPENIA

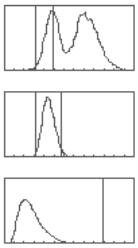
CBC mode

ORPHEE-MEDICAL
Presentation Results MYTHIC 22

Name :
Comments :
Patient Id :
Sample Id : 00018
Type : STANDARD

Operator ID : SAS Date : 14/12/2005 11:27:30 Seq# : 00033

	Result	Flags	Unit	Normal limits
WBC	5.8		10^3/l	4.0 / 12.0
RBC	5.14		10^6/l	4.00 / 6.20
HGB	15.4		g/dl	11.0 / 17.0
HCT	46.3		%	35.0 / 55.0
MCV	90.0		m^3	80.0 / 100.0
MCH	29.9		pg	26.0 / 34.0
MCHC	33.2		g/dl	31.0 / 35.5
RDW	13.2		%	10.0 / 16.0
PLT	301		10^3/l	150 / 400
MPV	8.1		m^3	7.0 / 11.0
PCT	0.243		%	0.200 / 0.500
PDW	12.7		%	10.0 / 18.0



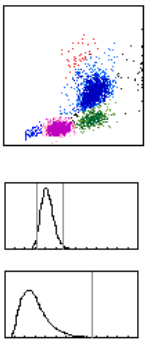
FLAGS:

5.8.1 PCL6 model report

Name : CARMONA
Comments :
Birth :
Gender : Test :
Patient Id : 2355488
Sample Id : 48-demo
Type : 2
Coll :

Operator ID : OM Date :
Seq# : Rack/

	Result	Flags	Unit	Normal limits
WBC	8.7	*	10^3/l	4.0 / 12.0
LYM%	35.8		%	25.0 / 50.0
MON%	10.7	h	%	2.0 / 10.0
NEU%	49.3	l	%	50.0 / 80.0
EOS%	4.1		%	0.0 / 5.0
BAS%	0.1		%	0.0 / 2.0
LYM	3.1		10^3/l	1.0 / 5.0
MON	0.9		10^3/l	0.1 / 1.0
NEU	4.3		10^3/l	2.0 / 8.0
EOS	0.4		10^3/l	0.0 / 0.4
BAS	0.0		10^3/l	0.0 / 0.2
RBC	4.46		10^6/l	4.00 / 6.20
HGB	13.5		g/dl	11.0 / 17.0
HCT	42.2		%	35.0 / 55.0
MCV	94.6		fl	80.0 / 100.0
MCH	30.3		pg	26.0 / 34.0
MCHC	32.0		g/dl	31.0 / 35.5
RDW	12.2		%	10.0 / 16.0
PLT	264		10^3/l	150 / 400
MPV	8.7		fl	7.0 / 11.0



L1RLN1N-
MONOCYTOSIS NEUTROPENIA
ATYPICAL LYMPHOCYTES ERYTHROBLASTS

PLATELET AGGREGATES

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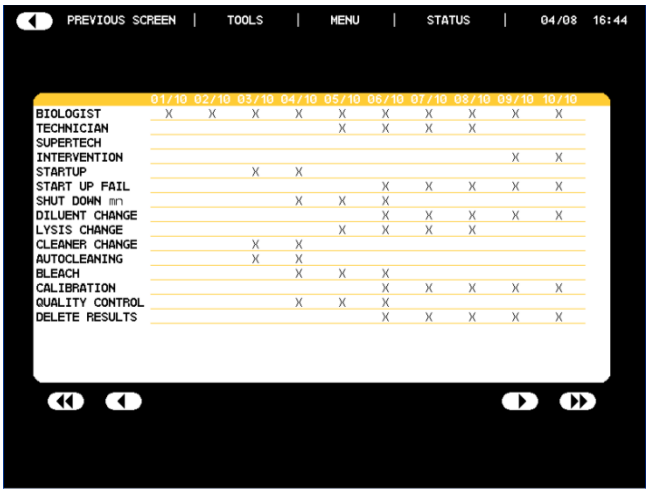
5.9 LOGS INTERVENTIONS

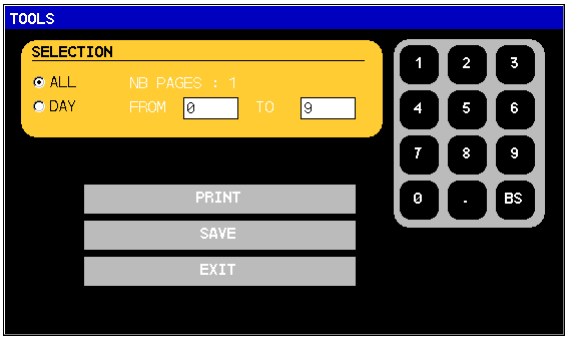
From the main menu, press LOGS to reach the logs' display

- **MYTHIC 22 AL** manages a simplified log allowing to save and display all the events performed each day for the following actions:



- **BIOLOGIST**: Login with the Biologist password.
- **TECHNICIAN**: Login with the service Technician password.
- **SUPERTEC**: Login with the "Super" service Technician password.
- **INTERVENTION**: An intervention or maintenance has been performed.
- **START UP**: Start Up cycle has been performed.
- **START UP FAIL**: Start Up cycle has failed.
- **SHUT DOWN**: Shut down cycle has been performed.
- **DILUENT CHANGE**: Diluent replacement.
- **LYSIS CHANGE**: Lysis replacement.
- **CLEANER CHANGE**: Cleaner replacement.
- **AUTOCLEANING**: Auto cleaning cycle.
- **BLEACH**: Bleach cycle.
- **CALIBRATION**: Calibration.
- **QUALITY CONTROL**: Quality control
- **DELETE RESULTS**: Results deleted in Archive.

Each column is identified by its date.



- To print or save the log report, press TOOLS
- Select ALL to print or save the logs of the number of pages indicated on the screen.
- To print or save the logs of one or more days, select DAY then enter the starting day and ending day.

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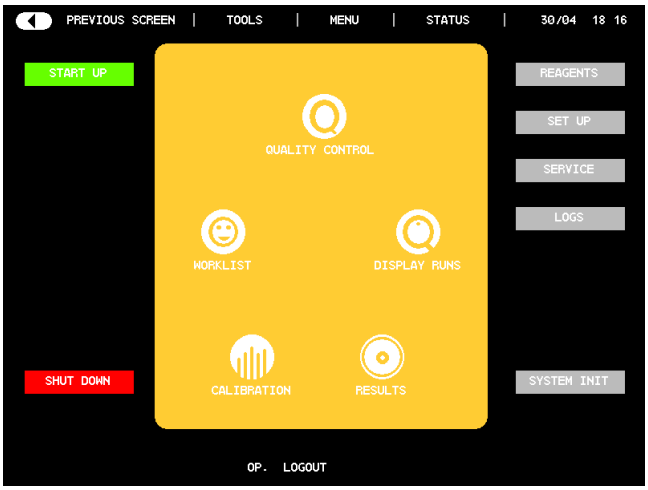
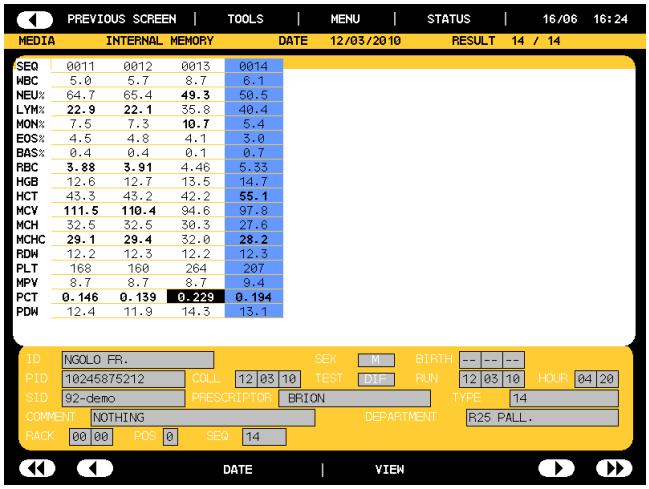
5.10 ARCHIVE

MYTHIC 22 AL can save more than the last 1500 patients with results, alarms, distribution curves in the internal memory and up to a maximum of 60 000 results in a memory stick (USB key) of 512 Mbit or more (see section 3.4.7).

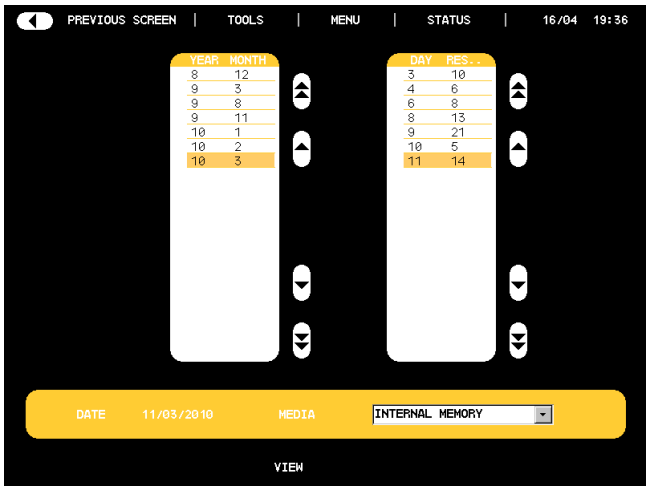


- Press to enter the archive display.

5.10.1 Results



- The Archive display allows viewing the results of the analysis.
- Each result is saved in a work list of the day.
- The first column gives the name of the different parameters, the first line the result number.
- The results of the patients are given in column.
- A value in bold means out of the normal limit and a value in white on black mean rejection.
- At the bottom of the display, under the table, are the demographic data of the selected result.
- The buttons , located under the table, allow changing pages.
- To find a result in the list, select the required **SEQ** number; press on the column of the result.
- To view an entire result, select the required result (identified in blue), then press **VIEW** (see section 5.10.2 hereafter).



- **DATE** allows an access to the results date list.
- Select the right year, month and day to display the results.
- The column RES indicates the number of results in memory.
- Press **VIEW** to see the table of results.

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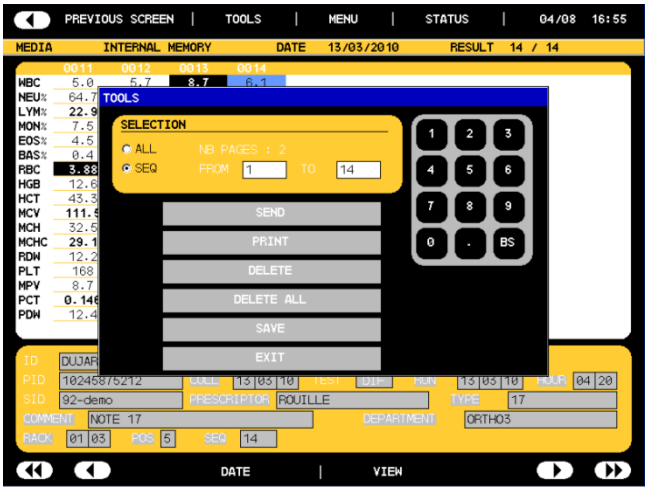
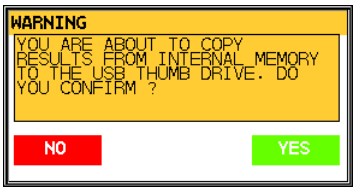


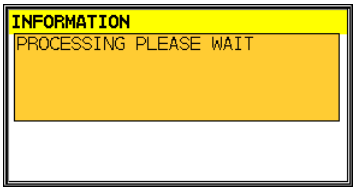
- To print, send, delete or save (in an USB key) results, press **TOOLS**

- It is possible to print, send, delete or save (in a USB key) :
  . All results: Press ALL
  . NB PAGES : 10 for printing.
  . Selected results: Select the first and the last results: SEQ # FROM 1 TO 99 with the numeric keyboard.
- Then press on **SEND**, **PRINT**, **SAVE and DELETE** (the selected result) or **DELETE ALL**.
- To exit the prompt without action, press **EXIT**.

NOTA: the printed report is a **list** of all selected patients.



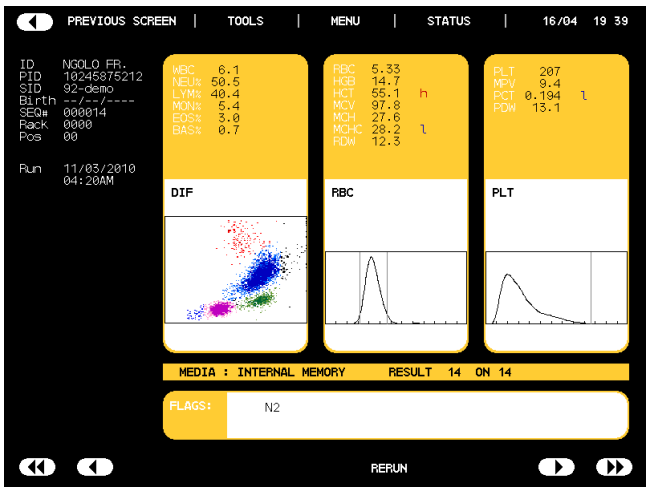
	If you press YES, the selected results will be deleted from the internal memory and stored in the USB key.



- This prompt allows follow-up the storage.

- This prompt informs that the storage has been unsuccessful, try another USB key.

5.10.2 View



- Keys ◀◀ ◀ and ▶ ▶▶ allow displaying each result and its identification.

- To send, print, delete or save results press **TOOLS**.

- The printed report covers one full page with one or two results per page.

- To come back to the archive main page, press ◀ **PREVIOUS SCREEN**.

- To come back to the Main Menu, press **MENU** .

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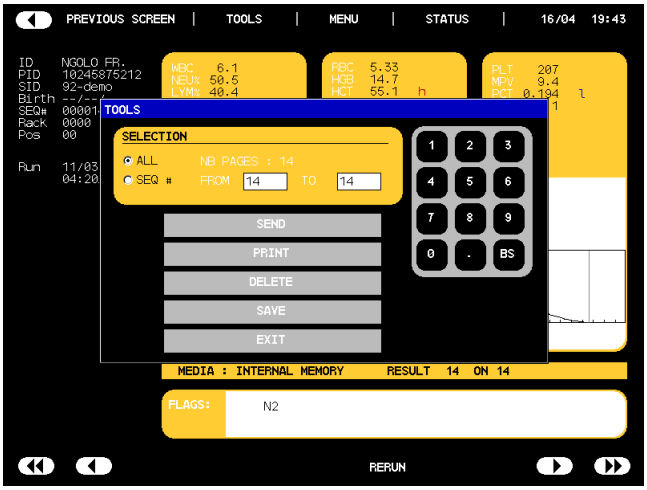
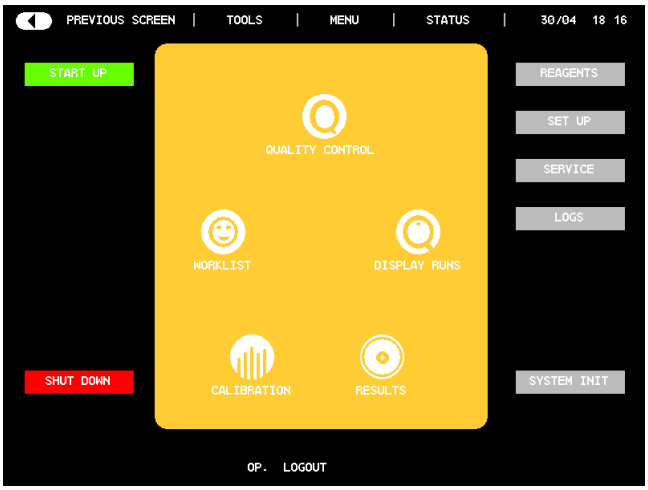


- To send, print, delete or save results, press **TOOLS**.
- It is possible to send, print, delete or save:
  . All results: Press ALL
  . NB PAGES : 10 for printing.
  . Selected results: select the first and the last results: SEQ # FROM 1 TO 99 with the numeric keyboard.
- Then press on **SEND**, **PRINT**, **and DELETE** or **SAVE**.

- To exit the prompt without action, press **EXIT**.

5.11 STAND BY AND SHUT DOWN



- From the main menu, press **SHUT DOWN**. **MYTHIC 22 AL** automatically performs a shut down cycle.
- All the hydraulic circuits are rinsed, and then cleaned with the cleaning solution.
- At the end of the cycle, **MYTHIC 22 AL** automatically stops.
- Shut Down can be automatically performed after a setting time (see section 3.4.6)

NOTA: After a shut down, it is impossible to perform an analytical cycle without launching a start up cycle. (see section 5.2)

MYTHIC 22 AL must stay at rest with cleaning solution during three hours every 24 hours or replaced by a bleach cleaning done each day instead of each week (see section 9.1.2).

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6. QUALITY CONTROL

6.1 INTRODUCTION

Quality control allows checking the stability of the **MYTHIC 22 AL** analytical performances when operating.
Orphee recommends using the following controls:
- **Myt-5D** tri level code number MYT502
- **Myt-5D** Normal level code number MYT506

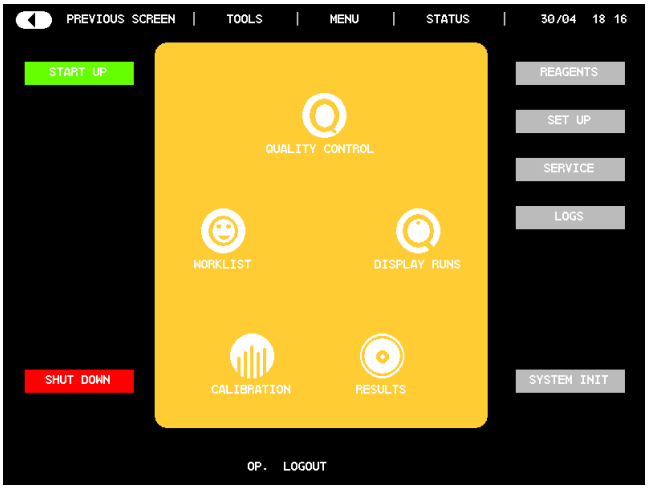
⚠	**The control blood must be used before its expiry date and stored according to the manufacturer's instructions for use. It must be well-mixed before use according to the instructions for use.**

In case of no specific local regulations, it is recommended to run a control blood at the beginning of each working day before running sample.
In case of exceeding the tolerances indicated on the blood control result sheet, it is recommended to perform a calibration (see section 7).

⚠	**In the case of use of local blood controls or national hematology survey a difference can be observed on the WBC result. This is done by the measurement techniques used in the MYTHIC 22AL. See the section 8.2.2.**

6.2 QUALITY CONTROL

MYTHIC 22 AL stores in memory up to 100 results per lot for 12 different lots. Results of each lot can be viewed in tables and Levey-Jennings graph.



- Press to have access to the quality control menu.

- Quality control display presents the identification of the lots.
- The last active lot is labeled with a dark dot on the left lot.
- To choose another lot, press on the required lot.
- The key CHANGE allows the modification of the identification and the target values.
- The key RESTORE allows restoring the data from an USB key.
- The key RESULT allows:
  . To view the result table.
  . To perform quality control analysis.

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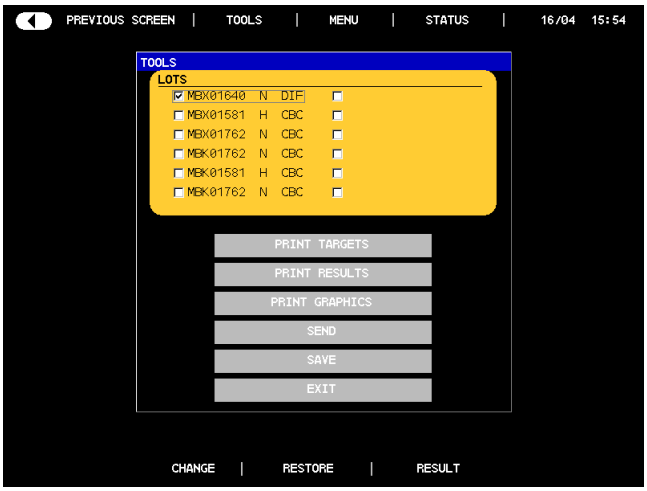
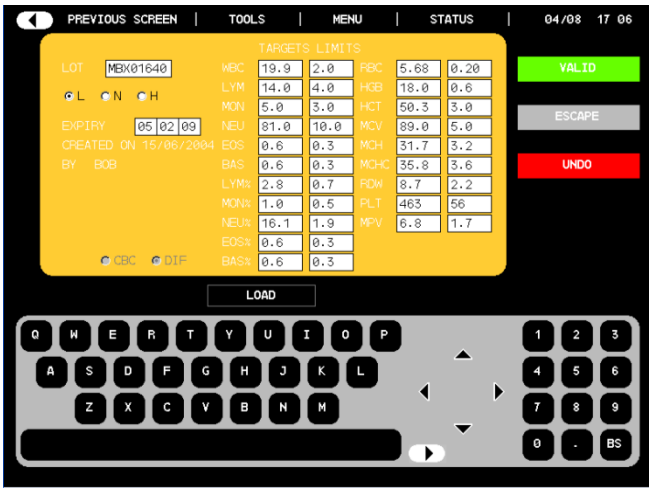


- To print or send the targets, results and graphics, press **TOOLS**

- Tag the lot number to select, then press the appropriate button.
  - **PRINT TARGETS**: print the targets.
  - **PRINT RESULTS**: print the results.
  - **PRINT GRAPHICS**: print the LJ graphics.
  - **SEND**: to send targets, results and graphics to a host.
  - **SAVE**: to save targets, results and graphics in the USB key.
  - **EXIT**: to leave the tool without action.

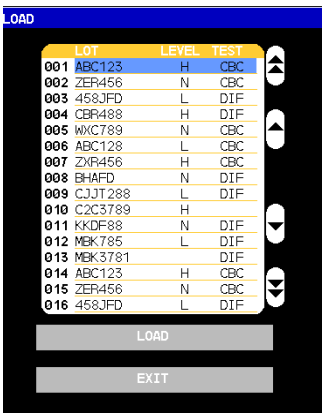
6.2.1 Change



- In this display, the user can enter the:
  - Lot number
  - Expiry date
  - Target values and tolerances
  - Level
  - Select DIF or CBC mode.

- To load target values and limits press **LOAD**.

- To validate or not the modification, see section 8.7.1



- The prompt display the lots available in the USB key.

- Select the good lot and press **LOAD**.

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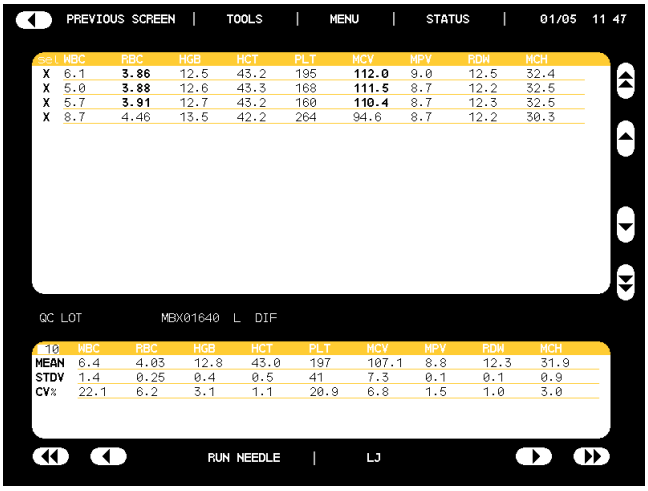
6.2.2 Run control blood

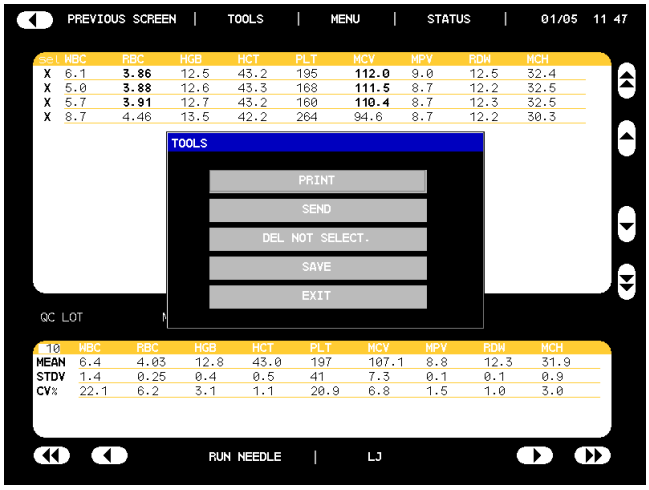


This screen allows running a control blood to check the precision of the **MYTHIC 22 AL**.

- To run a control blood analysis in open tube mode,

  o Press **RUN NEEDLE** and repeat this operation as long as needed (maximum **20** runs).

- The results are displayed in line, run after run.
- The statistics calculations are shown at the bottom of the display and are automatically done after each run.
- The column **SEL** allows selecting or unselecting a result (the statistics are done with the selected results only).



- To print, send or delete a result selected, press **TOOLS**.

- Press **LJ** to open the Levey-Jennings graph screen.

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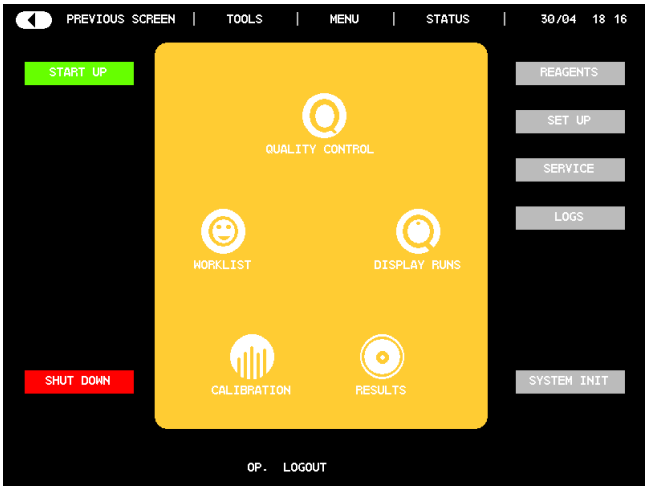
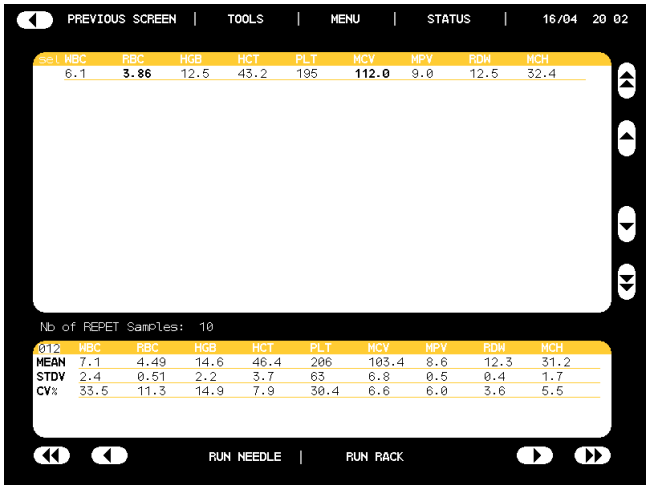
6.3 REPEATABILITY



- To run repeatability, first press SERVICE



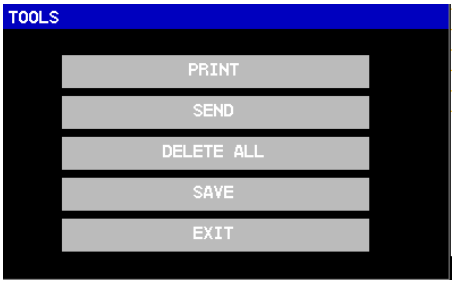
This screen allows carrying out a test of repeatability on all the parameters measured by the **MYTHIC 22 AL**.

- To run repeatability analysis in Rack mode:
  - o Check the number of sampling (to change, see section 3.4.4)
  - o Enter the RAC/POS of the sample to analyze
  - o Press RUN RACK

	It is mandatory to change for a new cap after a maximum of 20 piercings.

- To run repeatability in open tube mode:
  - o Press RUN NEEDLE and repeat this operation as long as needed (maximum **20** runs).

- The results are displayed in line, run after run.
- The statistics calculations are shown at the bottom of the display and are automatically done after each run.
- The column **SEL** allows selecting or unselecting a result (the statistics are done only with the selected results).



- The key TOOLS allows doing the following actions:
  - o **PRINT**: Print the table.
  - o **SEND**: Send the results.
  - o **DELETE ALL**: Delete all the results.
  - o **SAVE**: Save the results in USB key.
- Press **EXIT** to exit the prompt without action.

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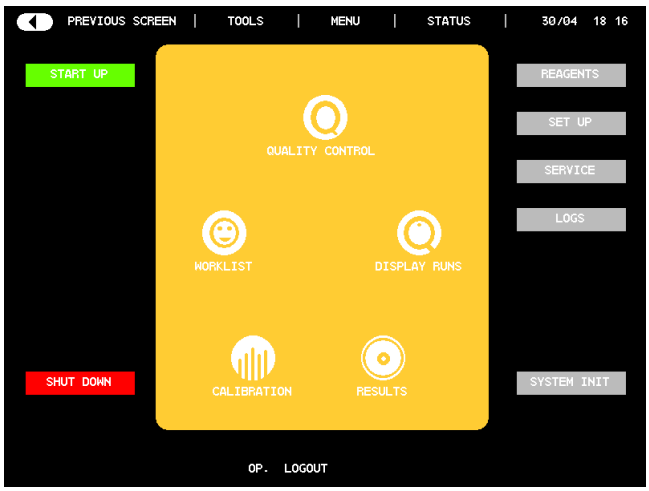
7. CALIBRATION

	The calibration of the MYTHIC 22 AL should be carried out only if the QC carried out on a blood control used according to the recommended conditions is significantly out of the limits (see section 6).

Orphee recommends using the following calibrator:
- **Myt-Cal** code number MYTCAL2

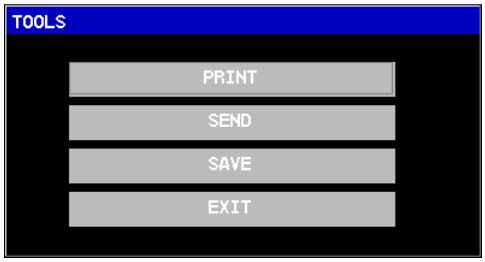
	The calibration blood must be used before its expiry date. It should be mixed and stored in accordance with the instructions of use recommended by the manufacturer.



- To reach the screen Calibration, press the key

from the main menu.

- This menu sends the following information:
  - Lot number of the last used calibrator.
  - The expiry date of the current lot.
  - The last date of calibration.
  - The operator's name.
  - The target values.
  - The current coefficients of calibration.
- To enter new values or to modify the values, press **CHANGE**.
- To calibrate, press **RUN**.



- Press **TOOLS**, then
  - **PRINT**: to print these information (see the print out report above).
  - **SEND**: to send these information.
  - **SAVE**: to store these information in the USB key.
  - **EXIT**: to leave the TOOLS without modification.

NOTA: If the **M** letter appears on the right of the date of calibration, that means that the last calibration was done by manual modification of the calibration factor (see section 3.4.5)

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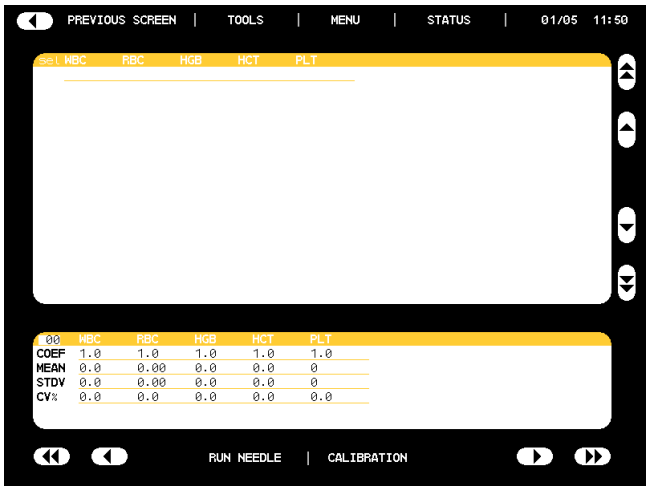
7.1 RUN CALIBRATOR

7.1.1 Calibration blood analysis

This screen allows running analysis on calibration blood to perform the **MYTHIC 22 AL** calibration.



This screen allows carrying out the calibration on the parameters measured by the **MYTHIC 22 AL**.

- To run calibration in open or other vial tube mode:
  - Press **RUN NEEDLE** and repeat this operation as long as needed (maximum 10 runs).

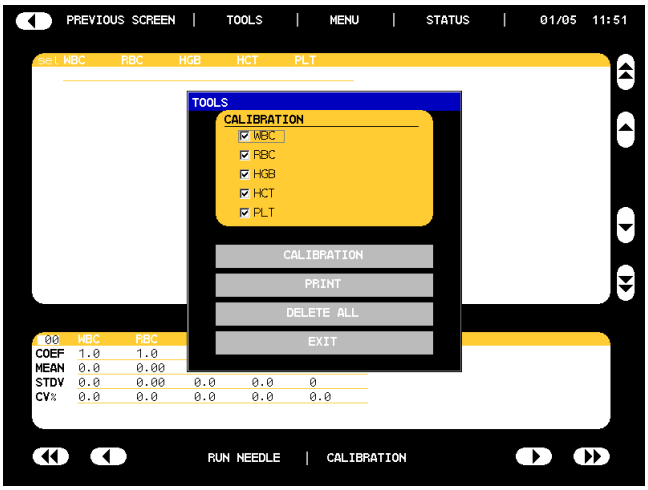
- The results are displayed in line run after run.
- The statistics calculations are shown at the bottom of the display and are automatically done after each run.
- The column **SEL** allows to validate or to unselect a result.

- To calibrate, see the following section hereafter.

NOTA: The results of the analyses performed on one calibrator during the same day remain in the memory and are used for calculations if they are selected.

7.1.2 Calibration

	Before starting the calibration, unselect the results you do not wish to use for the calculation of the calibration (See below section 7.1.1).



- From the previous menu the key **CALIBRATION** or **TOOLS** allows:
  - To calibrate with the selected results.
  - To delete the results. Press **DELETE ALL**
  - To print the results. Press **PRINT** (see below the print report)
- To calibrate one or more parameters:
  - Select the parameter
  - Press the key **CALIBRATION**
- To exit without action, press **EXIT**

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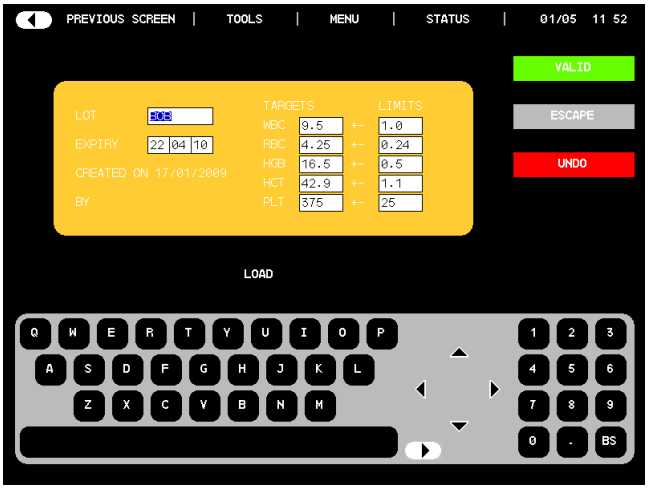
Model of print out calibration report:

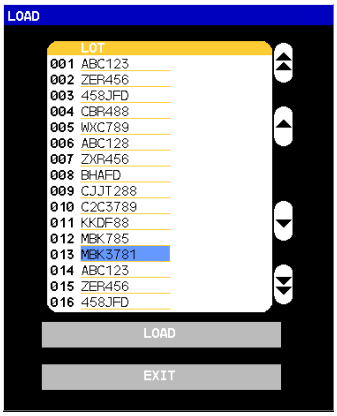
```
CALIBRATION IN PROGRESS                    SERIAL NUMBER:   000000-000000
                                           SOFT VERSION      V0.5.x
PRINTED ON :   19/06/2004 15:50:00         BY   BILL

COEFFICIENTS : 1.000   1.000   1.000   1.000   1.000

LOT CS224
CREATED ON     18/12/2003 BY  BILL
EXPIRY         06/01/2004

            WBC   RBC   HGB   HCT   PLT
TARGETS     9.5   4.25  16.5  46.9  375
LIMITS      1.0   0.24  0.5   2.1   25

COEF        1.0   1.0   1.0   1.0   1.0
MEAN        0.0   0.00  0.0   0.0   0
STDV        0.0   0.00  0.0   0.0   0
CV%         0.0   0.0   0.0   0.0   0.0
```

7.2 TARGET VALUES MODIFICATIONS



- To modify information relative to a batch or to create a new batch, please follow the following steps:

- From **Calibration Menu**, press **CHANGE**.
- Select the lot number CS224
- Select the field to be modified.
- Enter your new value with the numerical keyboard or with the alphabetical keyboard.
- Press **LOAD** to load the target and tolerances values and expiry date and lot number from an USB key.
- To validate or not the modification, see section 8.7.1.



- The prompt display the lots available in the USB key.

- Select the good lot and press **LOAD**.

	Any modification (lot number, date or target values) involves the deletion of all the associated results still in memory.

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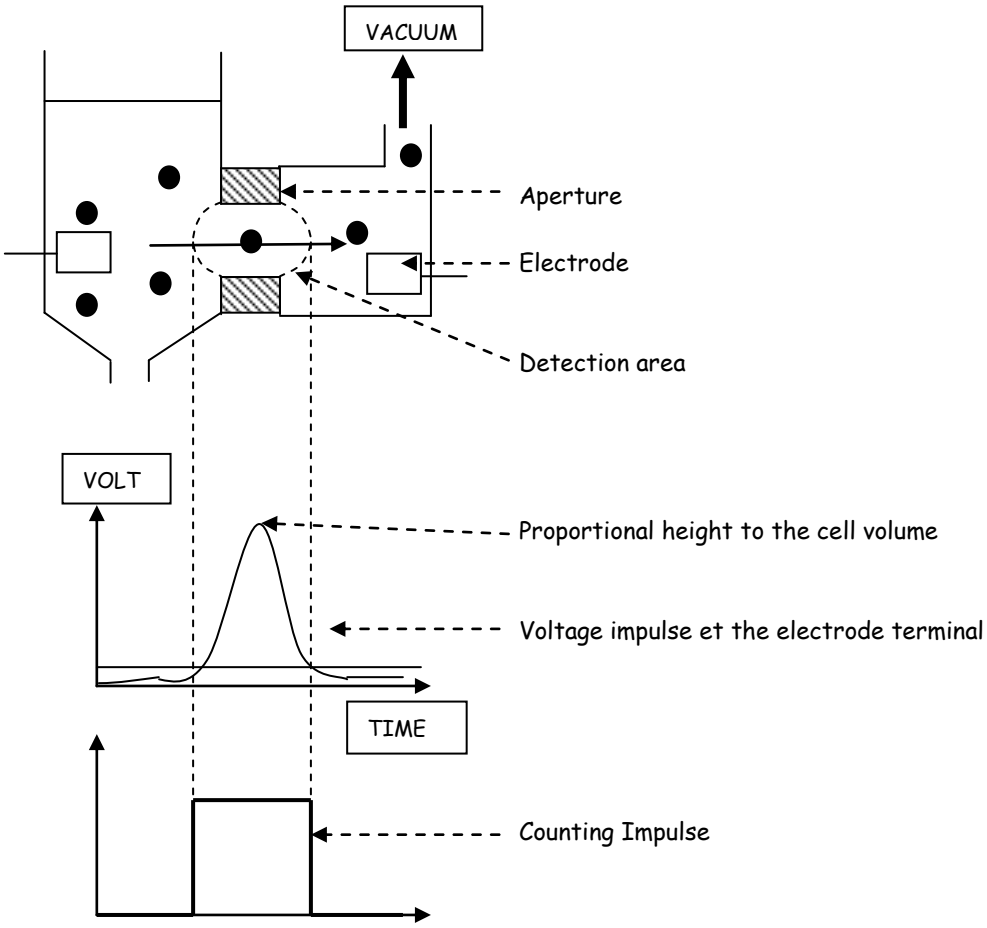
8. TECHNOLOGY

The innovative technology of the **MYTHIC 22 AL** is covered by **six** filed or pending patents. A new innovative concept of optical measurement system and a unique lysing reagent were developed to obtain a so small and powerful analyzer.

8.1 DETECTION PRINCIPLE

8.1.1 WBC, RBC, PLT Counting

The counting of the cellular elements in a blood sample is done with the impedancemetry technique.
This technique is based on the modification of the impedance of a calibrated aperture soaking in an electrolyte and going through a constant course delivered by two electrodes located on both sides of the aperture.
A vacuum applied on a side of the aperture allows the cells passage. They oppose their physical volume to the course passage. A voltage impulse is registered at the electrodes terminal. The height of this impulse is proportional to the cell volume.



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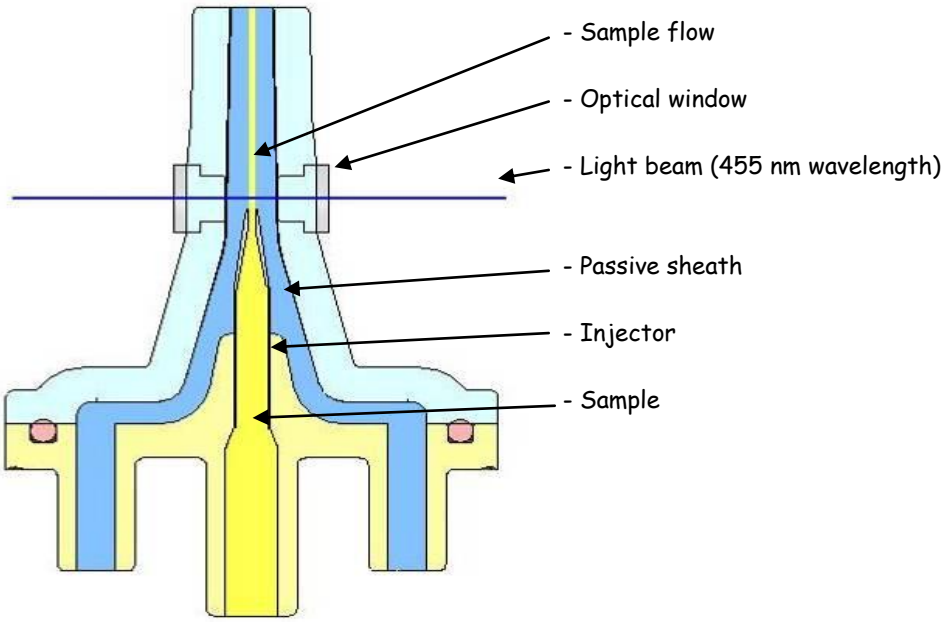
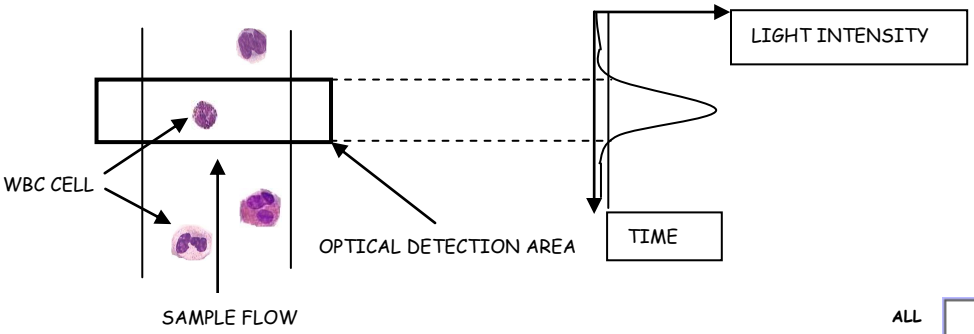
8.1.2 Five part diff measurement

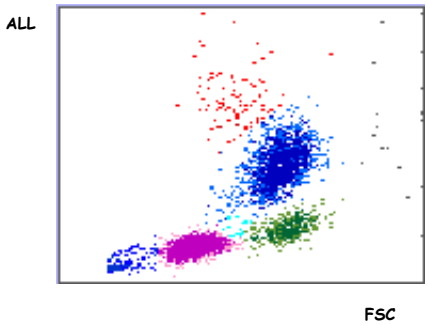
The innovative optical detection system is covered by two pending patents. This technology (called **OCHF** for **O**ptical **C**ytometer **H**ydrofocus **F**ree) is based on an unique and innovative concept of an active sample flow and a passive sheath.
The sample flow is introduced in the flow cell under pressure and the sheath is only dedicated to maintain it.
This principle enables to introduce a large quantity of samples and to use a great dilution rate (which allows doing the Hemoglobin measurement with the same dilution).
The main advantages are:

- High level of reliability of the optical adjustment.
- Only two measurement axes for five parameters.
- High resolution matrix.
- Only one passive sheath with low reagent consumption.
- No hydro focusing system.
- Low level of contamination between two measurements.
- Very low cost flow cell (injected plastic).





For each cell throwing the optical detection area, two pulses are generated, one for the Axis Loss Light (ALL) measurement and one for the Forward Side SCatter (FSC) measurement.
The result of those two axes of measurement is the high definition matrix that enables to identify five WBC populations.



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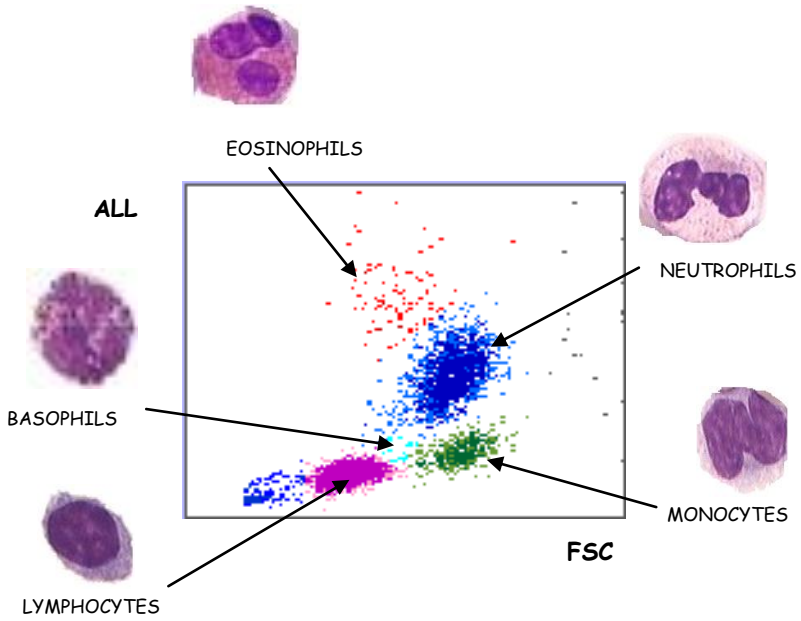
The five part diff is obtained by the optical matrix analysis after action of the lytic reagent (pending patent). This reagent destroys the RBC and their stromas, composes the oxy hemoglobin chromogen and protects the white blood cell membrane to keep it in closed native state.



8.1.3 Hemoglobin measurement

The hemoglobin measurement is directly done in the WBC chamber, by spectrophotometry at 555 nm. Hemoglobin is detected by formation of a chromogen oxy hemoglobin type (cyanide free technique).
A measurement of the blank of hemoglobin is done for each analytic cycle and during the start up rinsing step.
An automatic offset circuit for the LED 555 nm allows maintaining the blank level at the same range. It is not necessary to adjust this range with a potentiometer.

8.2 LEUKOCYTE ANALYSIS

8.2.1 Measurement

The leukocyte number analysis is done by impedancemetry in the WBC counting chamber; the other ten parameters are obtained by flow cytometry measurement (see section 8.1.2):
All the thresholds of the differential are adjustable in the 20 blood types (see section 3.4.4.2)

Parameters		Pathologies (adjustment section 3.4.4.1)
WBC	White Blood Cells	Leukocytosis : WBC>WBC h Leucopenia : WBC<WBC b
LYM%	Lymphocytes in percentage	Lymphocytosis : LYM>LYM h (% &/or #) Lymphopenia : LYM<LYM b (%&/or #)
LYM#	Lymphocytes in value	
MON%	Monocytes in percentage	Monocytosis : MON>MON h (%&/or #)
MON#	Monocytes in value	
NEU%	Neutrophils in percentage	Neutrophilis : NEU > NEU h (%&/or #) Neutropenia : NEU < NEU b (%&/or #)
NEU#	Neutrophils in value	
EOS%	Eosinophils in percentage	Eosinophilis : EOS > EOS h (%&/or #)
EOS#	Eosinophils in value	
BAS%	Basophils in percentage	Basophilis : BAS > BAS h (%&/or #)
BAS#	Basophils in value	

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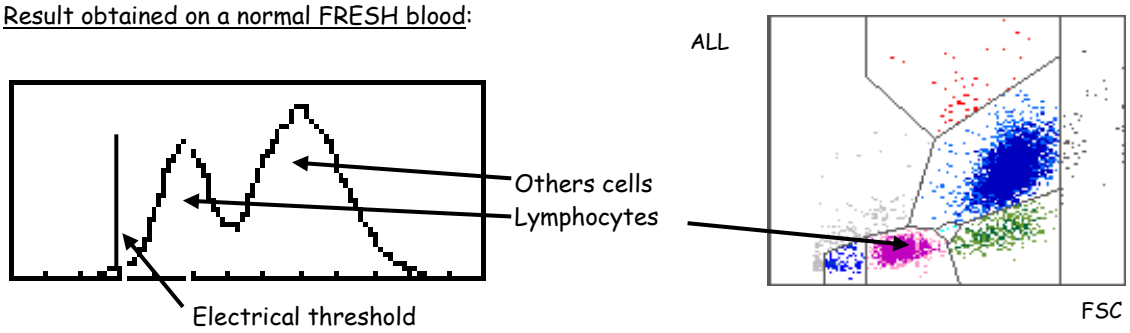
8.2.2 Local blood control limitations

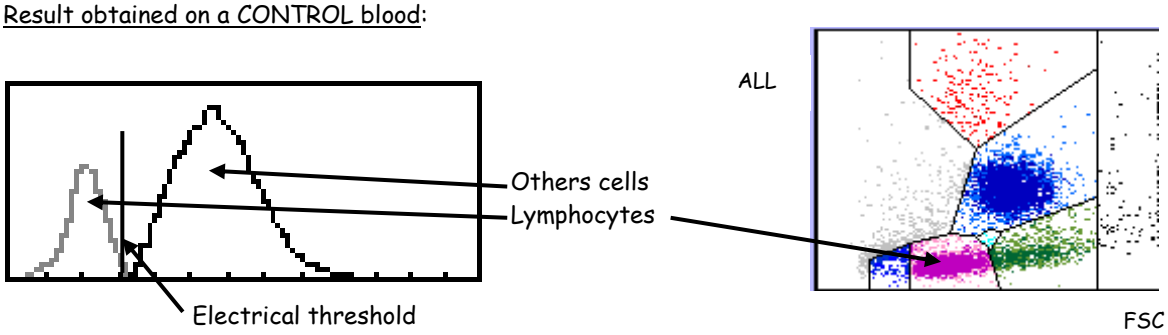
	In the case of use of local blood controls or national hematology survey a difference can be observed on the WBC results. This is done by the measurement techniques used in the MYTHIC 22AL. The WBC can be lower than the expected results.

Result obtained on a normal FRESH blood:



The number of WBC is done by counting all the cells in the curve between the electrical threshold to the end of the curve.
The left peak is the lymphocytes and the right peak all the others WBC cells.

Result obtained on a CONTROL blood:



For a control blood, in order to allow to have the lymphocytes in the lymphocyte area in the scattergram, the manufacturer of the control bloods must use smaller fixed cells which appears, for the lymphocytes, under the electrical threshold on the WBC curve and therefore, are not considered.

The use of smaller cells is necessary because the fixation of the membrane increase the measurement of the FSC signal. The fixed membranes of the cells give a more important deviation of the light beam compare to the same membranes without fixation. It is well-known in cytometry than the use of fixed cells increase the FSC signal.

It appears therefore evident that, regarding a control blood, the resistive WBC counting is lower than the real number of cells inside the control blood.

The local blood controls manufacturers or national hematology survey providers must be informed of this limitation.

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8.3 ERYTHROCYTE ANALYSIS

The erythrocyte analysis is done by impedancemetry in the RBC counting chamber and by analysis of the hemoglobin inside WBC chamber as previously described. Seven parameters are obtained:

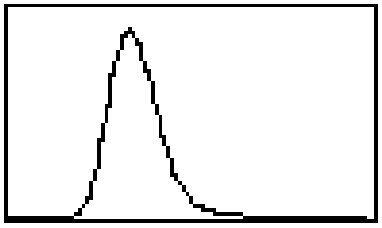
Parameters		Pathologies (adjustment section 3.4.4.1)
RBC	Red Blood Cells	Erythrocytosis : RBC>RBC h
HGB	Hemoglobin	Anemia : HGB < HGB b
HCT	Hematocrit	
MCV	Mean Corpuscular Volume	Microcytosis : VMC<VMC b Macrocytosis : VMC>VMC h
MCH	Mean Corpuscular Hemoglobin	
MCHC	Mean Corpuscular Hemoglobin Concentration	Hypochromia : MCHC<MCHC b Cold Agglutinin : MCHC>MCHC h
RDW	Red blood cells Distribution Width	Anisocytosis 1 : RDW>RDW h1

Hematocrit (**HCT**) is measured by integration volume of all of the red blood cells which flow in the RBC counting chamber aperture.
MCV is obtained by calculation, following the formula:

$$\mathbf{MCV} = \frac{HCT \cdot 10}{RBC}$$

The RBC distribution curve analysis allows the measurement of **RDW**. RDW is an expression of the standard deviation divided by MCV. This parameter evaluates the RBC anisocytosis.

$$\mathbf{RDW} = \frac{k \cdot SD}{MCV}$$



Wintrobe constant calculation:
The Mean Corpuscular Hemoglobin (MCH) calculation is made from HGB and RBC by the formula below:

$$\mathbf{MCH} = \frac{HGB \cdot 10}{RBC}$$

The Mean Corpuscular Hemoglobin Concentration (MCHC) is made from HGB and HCT by the formula below:

$$\mathbf{MCHC} = \frac{HGB \cdot 100}{HCT}$$

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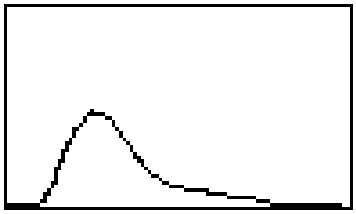
8.4 ANALYSIS OF PLATELETS

Platelet analysis is made by impedancemetry in the RBC counting chamber at the same time with red blood cells. Four parameters are obtained:

Parameters		Pathologies (adjustment section 3.4.4.1)
PLT	Platelets	Thrombopenia : PLT<PLT b Thrombocytosis : PLT>PLT h
MPV	Mean Platelet Volume	Giant platelets : MPV> MPV h
PDW	Platelet Distribution Width	
PCT	Thrombocrit	

The analysis of the platelet distribution curve allows measuring the Mean Platelet Volume (**MPV**) and the Platelet Distribution Width (**PDW**).
Thrombocrit (**PCT**) is made from PLT and MPV by formula below:



$$\mathbf{PCT} = \frac{PLT \cdot MPV}{10000}$$

8.5 FLAGS

MYTHIC 22 AL manages 25 different flags. These flags allow the user to be warned if there is a problem which may affect the quality of the results. All of these flags appear on the right of the result.

	In presence of one or more flags, it is recommended to check the result by a conventional measure or on blood smear.

NOTA: Most of these flags can be modified by the user (see section 3).

8.5.1 General Flags

The following alarms are common for all parameters.
XXX *****: Counting or measure rejection; can appear with WBC, RBC, PLT and HGB (see section 8.5.3 for HGB and section 8.5.2 for DIF parameters).
XXX**D**: Higher than linearity limits but lower than the reportable limits. WBC, RBC, PLT, HCT, HGB.
+++D: Higher than the reportable limits. WBC, RBC, PLT, HCT, HGB.
----: Rejected value.
h: results higher than normal value.
b: results lower than normal value.
H: results higher than panic value.
B: results lower than panic value.

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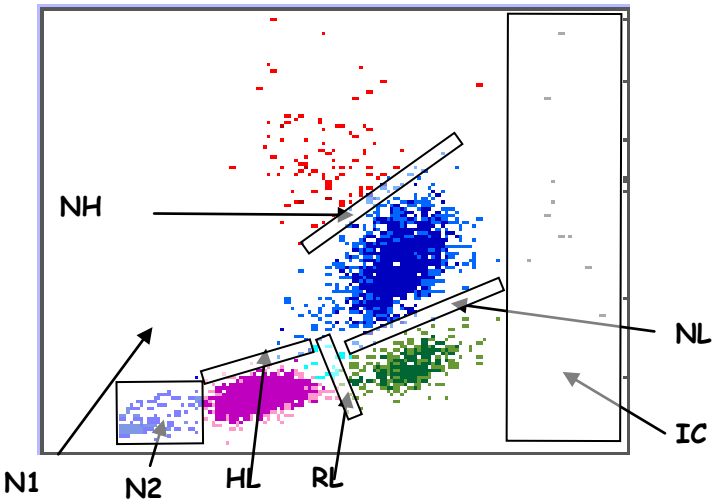
8.5.2 Instrument Flags

W_CL: Suspicion of WBC aperture clog, if it persists, run a concentrated cleaning (see section 9.1.2).
R_CL: Suspicion of RBC aperture clog, if it persists, run a concentrated cleaning (see section 9.1.2).
O_CL: Suspicion of Optical injector clog, if it persists, run a concentrated cleaning (see section 9.1.2).
OPT- : Counting gap between resistive and optical WBC count, if it persists, run a concentrated cleaning (see section 9.1.2)
INS_H: HGB channel saturation, run a START UP cycle.
INS_T: A temperature (enclosure, reagents or ambient) is out of range (see section 9.5.2)
INS_P: Pressure default (see section 9.5.2).

8.5.3 Leukocytes Flags

SCATTERGRAM FLAGS:



All the followings flags' levels are adjustable in the 20 types of blood (see section 3.4.4).
Number of cells in a zone:

N1 (**N**oise **1**): Presence of platelet aggregate, debris or resistant RBC
N2 (**N**oise **2**): Presence of platelet aggregate, erythroblast or small lymphocytes.
IC: Presence of **I**mmature **C**ells (from the mono or polynucleated cells line)

Number of cells located of each side of the threshold:

RL (**R**ight **L**ymphocytes): Presence of atypical lymphocytes or basophils.
HL (**H**igh **L**ymphocytes): Presence of basophils, small Neutrophils (without granulations or few segmented), band cells.
NL (**N**eutrophils **L**ow): Presence of small Neutrophils (without granulations or few segmented), band cells or hyper basophil Monocytes.
NH (**N**eutrophils **H**igh): Presence of giant Neutrophils, hyper segmented Neutrophils, eosinophils with few granulations or damaged eosinophils.

- The WBC flags appear when the % **AND** # limits are reached.

⚠	**These flags may appear if the blood was not stored in good conditions or if it was sampled too many times (more than 20 times).**

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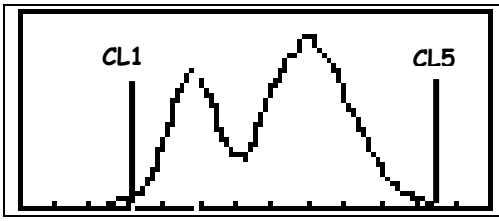
DIF parameters display rules:

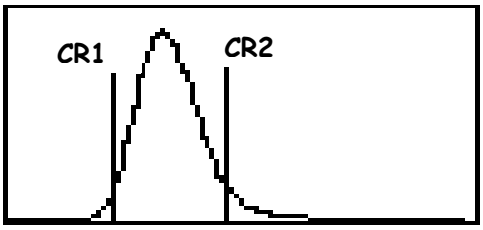
- If one or more DIF parameters (LYC, MON, NEU, EOS or BAS) are followed with a star (XXX *), the sample must be checked on smear.
- Basophil result must be checked on smear if it is followed by a star (XXX *).

WBC CURVE FLAGS:

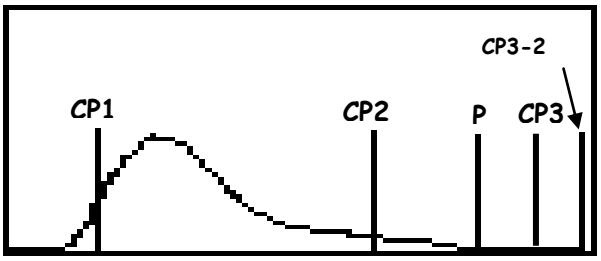
This curve is done by the WBC channel measurement and does not appear on the normal results screen. The flags L1 and L5 complete the flags N2 and IC.

	**L1** = Presence of platelet aggregate, erythroblast or small lymphocytes at the left of **CL1**. **L5** = Presence of immature cells at the right of **CL5**.

8.5.4 Erythrocyte and HGB Flags

	**R1** = Abnormal quantity of microcytes at the left side of **CR1**. **R2** = Abnormal quantity of macrocytes at the right side of **CR2**. **HGB:** * means bad measure of the HGB blank.

8.5.5 Platelet Flags

	**P1** = **0** to **CP1**: Presence of abnormal quantity of debris or small cells. **P2** = **P** to **CP2**: Presence of schizocytes. **P3** = **CP3** to **CP3-2**: Presence of microcytes.

- The RBC and PLT flags appear when the % limit **OR** # limit is reached

8.5.6 QC Flags

QC_F: QC Failed. This flag appears when the result of the QC run was out of the limits. This flag is printed with each result.

QC_ND: QC Not Done, this flag appears when no QC was run before the analysis of samples. This flag is printed with each result. See section 6.

8.5.7 STARTUP Flags

SU_F: STARTUP Failed. This flag appears when samples are run after a bad START UP. This flag is printed with each result.

SU_ND: STARTUP Not Done. This flag appears when samples are run without START UP running. This flag is printed with each result. See section 5.4.

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8.6 HYDRAULIC & MECHANIC DESCRIPTION

The hydraulic part of the **MYTHIC 22 AL** is very simple and made of these modules :

1 - Auto loader module.
2 - Sampling module.
3 - Counting bath module.
4 - Syringes module.
5 - Optical manifold.
6 - Optical bench.

The modules are connected together by semi rigid tubing.

8.6.1 Auto loader module

This module (patented) enables to load, transfer, mix and unload the racks. Ten racks of five tubes can be loaded. The loading can be done continually.
The racks are loaded on the guide rail by a loading screw then displaced by another screw (transfer screw). The rail which maintains the rack can also rotate for mixing the blood inside the tubes.
The blood is mixed by complete returning. Each sample is identified with the barcode reader before the sampling. Each rack is also identified by the barcode reader.
The speed mixing is 25 reversals per minute with a minimum of 20 reversals for a first mixing then 10 per minute.
The system allows the rerun of the sample before the displacement to the next sample tube (see section 3.4.1).
When all the samplings are done for a rack, it is unloaded by the unloading motor.

8.6.2 Sampling module

This module (two patents) enables to pierce the cap of the sample tube with one needle only, to draw the sample and to perform the WBC and RBC/PLT dilutions.
It is assembled with a rotating rocker moving around a support which maintains the system to move the sampling needle up and down. A very reliable system of rack-gear moves the rocker.
The cleaning system of the sampling needle can be removed without tool (see section 9.3.2).
The o-ring of the needle included in the cleaning system can also be removed without tool (see section 9.3.2). The maintenance of these parts is very easy to perform.

8.6.3 Counting bath module

This module allows to count the WBC and RBC/PLT and to measure the HGB.
It is made with a manifold maintaining the reagent commutation valves and the counting bath block with their measurement block including the apertures.
The counting bath block assembly and these apertures can be removed without tool (see section 9.3.3/4/5).

8.6.4 Syringes module

This module (two patents) enables:

To draw the sample
To distribute the reagents
To drain the baths
To do the vacuum necessary for counting
To push the waste to the waste container
To push the WBC sample and the diluent sheath, into the flow cell.

It is made with a manifold maintaining the fluid commutation valves and with the syringes block including five syringes:

The sampling syringe
The lysis syringe
The two waste and vacuum/pressure syringes
And the diluent syringe.

Single motor drives the five syringes.

8.6.5 Optical manifold

This manifold allows driving the different reagent towards the counting bath module or towards the optical bench. It maintains seven commutation valves.

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8.6.6 Optical bench

This very important part (two patents) allows measurement of the leucocytes sub population.
It is made of three parts:
- An illumination module which contains the semi conductor light source, a beam adjustment glass smear, and lens.
- A flow cell made of injected plastic in which the sample and the passive sheath flow away.
- And the detection module which contains lens, a beam separation glass smear, photodiodes and the amplifier boards for the two measurement axes.

8.7 SOFTWARE

8.7.1 Common Functionalities

Common buttons:

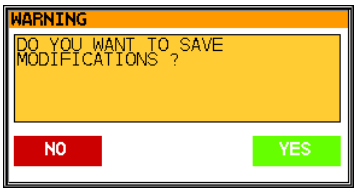
These four keys PREVIOUS SCREEN | TOOLS | MENU | STATUS located at the top of the screens are always present:
- PREVIOUS SCREEN allows to come back to the previous display.
- MENU allows to come back to the MENU display wherever you are in the arborescence.
- TOOLS depends on the screen, it allows to open a window dedicated to perform an action, for example to select information, to print, send, save or delete it.
- STATUS allows to check the status of the sampler.
- allow to move at the beginning or at the end of the table.
- allow to move on the right or on the left page by page or column by column.
- allow to go to the first or the last line of a table.
- allow to change for the previous or next page.
- A button in grey (RERUN) instead of white (RERUN)means that it is not available at this moment.

The following buttons are common for the screens where entries are possible:

VALID — Allows to leave the screen after modifications, a prompt appears to request a confirmation.

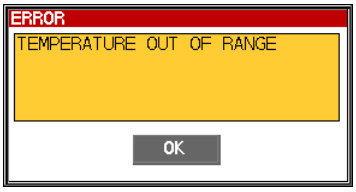
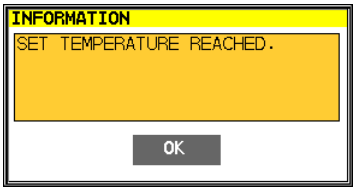
ESCAPE — Allows to delete the modification in progress in one box.

UNDO — Allows to cancel all modifications done in one or several boxes.



Once a modification is done, this prompt allows to save (press **YES**) or not (press **NO**) the modification.

Windows (prompts):

		
Means an **ERROR** occurred, it is **mandatory** to do the action described in the window or in the table section 9.6.	**WARNING**: You have to confirm or not the action described in the window.	**INFORMATION** window: no action required.

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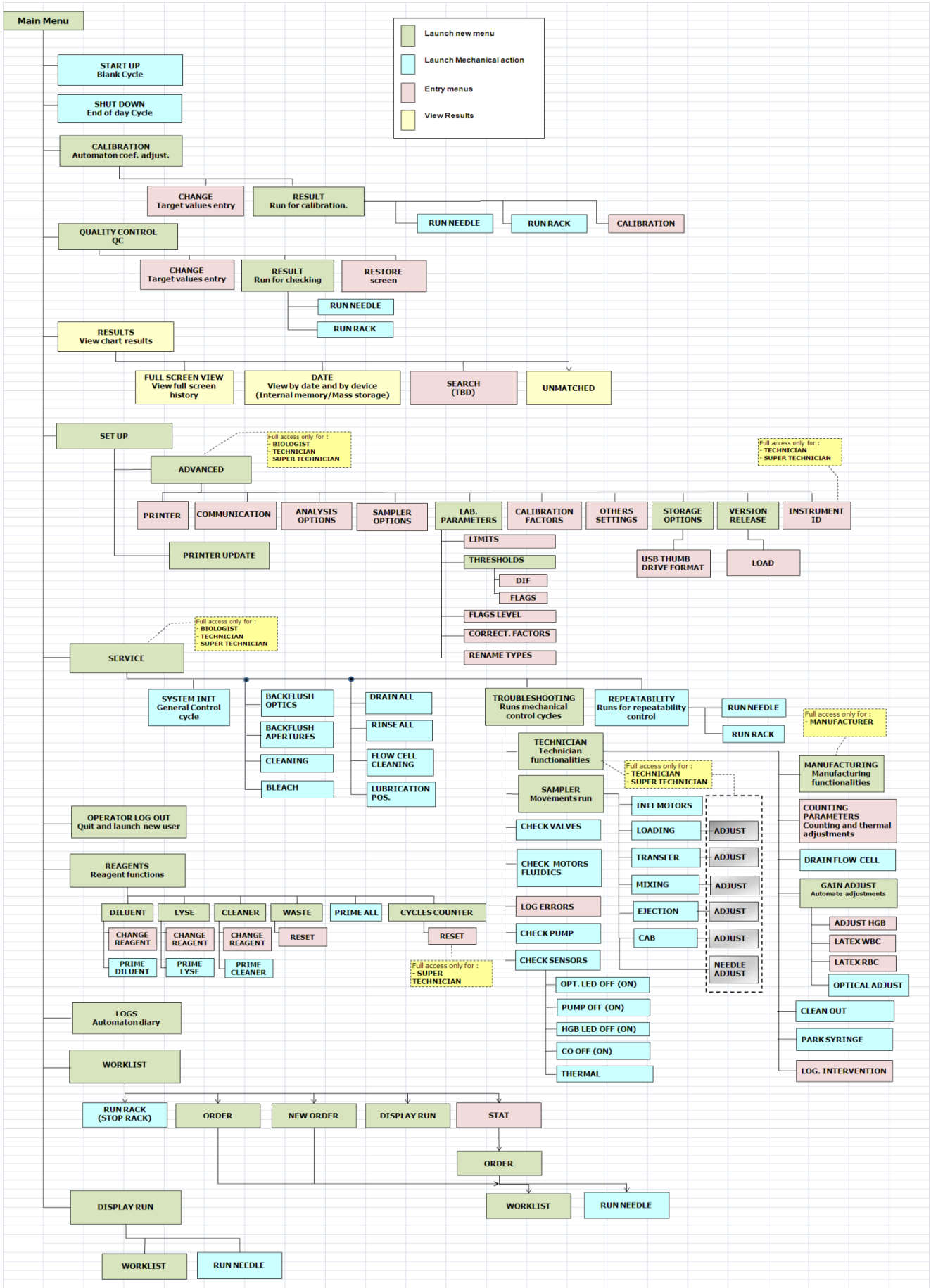
8.7.2 Menu tree



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9. SERVICE

The quality of the results and the reliability of the **MYTHIC 22 AL** are directly linked to the strict respect of the maintenance hereafter described.

	To perform the maintenance and the repair described in this section, it is mandatory to have been adequately trained, to wear rubber gloves and wash hands with a disinfectant after completion of work.

	After opening any doors or dismantle any parts, for performing a cleaning or a repairing, take attention with all metal sheets which can injure your fingers.

9.1 MAINTENANCE

9.1.1 Maintenance table

NOTA: This table is made for an average number of 150 samples per day. For more, please proportionally increase the number of maintenances.

MAINTENANCE	DAILY		WEEKLY		QUARTERALY (~11250 cycles)		HALF A YEAR (~22500 cycles)		ANNUALLY (~45000cycles)	
	User	Tech	User	Tech	User	Tech	User	Tech	User	Tech
Reagents level	X									
Start Up	X									
Automatic cleaning	X									
Concentrate cleaning			X							X
Shut down or concentrate cleaning	X									
Cover cleaning	X									X
Piston greasing					X					X
In line filter cleaning					X					X
Barcode cleaning					X					X
Needle o-ring replacement							X			X
Syringes o-ring replacement										X
Motor screw greasing										X

MAINTENANCE TO BE DONE BY THE USER (yellow boxes):
- Reagents level control: see section 5.3
- Start up: see section 5.2
- Automatic Cleaning: The cleaning is automatically performed by the **MYTHIC 22 AL** following the set up defined by the user (see section 3.3.6). (The standard value is 80).
Increase the frequency of the cleaning of the **MYTHIC 22 AL** in case of analyzes of pathological samples or if there are too many flags and too often.
- Concentrated cleaning: see the following section 9.1.2
- Shut down or concentrate cleaning: see section 5.11
- Cover cleaning: Clean the cover above and around the sampling needle with a wet paper with a disinfectant to eliminate the blood trace.
- Piston greasing: see section 9.1.3
- In line filter cleaning: see section 9.1.4
- Barcode cleaning: see section 9.1.5
- Needle o-ring replacement: see section 9.4.2

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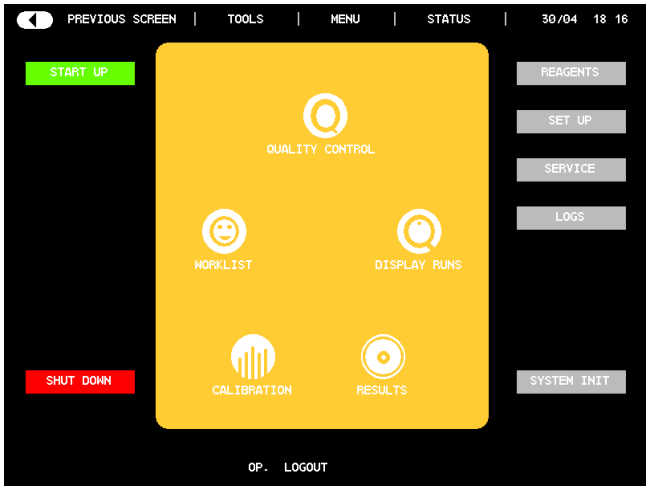
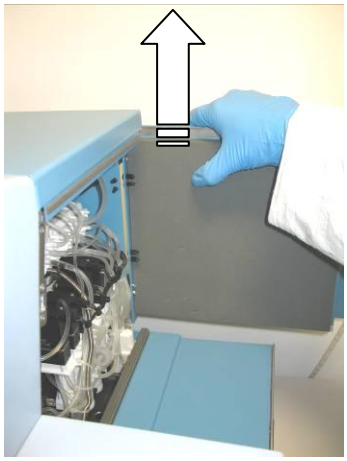
9.1.2 Concentrate cleaning

This cleaning is necessary once a week to clean the WBC bath or when **MYTHIC 22 AL** is in permanent rejection for at least one measured parameter or permanent clog flag (see section 8.1.5).
Prepare a Sodium Hypochlorite solution at 12° in chloride (diluted 4 times with distilled water if sodium hypochlorite is concentrated at 48° in chloride or three times with 36°).



- Return to the main menu by pressing MENU.
- Then press SERVICE.

- Press BLEACH.



- Wait for the prompt, then:
- Open the door on the right side by unscrewing the two quarter turn screws with the key provided in the kit.
- Open completely the door, then lift it to remove.

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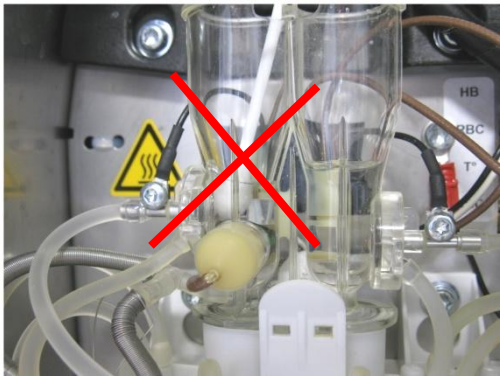
	Wear rubber gloves and wash hands with a disinfectant after completion of work.

- Put bleach in a container
- Then introduce the tip to wet it

- Clean the top of the bath (some traces of dried blood can remain) with the tip until the complete removing of the durst.



IMPORTANT NOTICE

	Never enter the tip inside the bottom of the bath, otherwise the counting electrode could be damaged and the results altered.

- Put **3** ml of sodium hypochlorite solution in each counting chamber.
- Close the door.
- Press the button in the window located in the middle of the screen.
- **MYTHIC 22 AL** performs a maintenance cycle of the apertures and the flow cell, followed with a standby mode during 2 min.
- After 2 min. **MYTHIC 22 AL** rinses all of the elements. Operator can perform an analytic cycle.

	Wear rubber gloves and wash hands with a disinfectant after completion of work.

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9.1.3 Piston greasing

- To have access to the hydraulic cycle, press SERVICE from the **MAIN MENU**, and then press LUBRIFICATION POS. to put the piston of the syringe module in the greasing position.

⚠	**Operators must be trained and should know that due to moving parts, there is a risk to pinch their fingers between pistons and the syringe body.**

☣	**Wear rubber gloves and wash hands with a disinfectant after completion of work.**

- Open the door on the right side and remove the unloading table (see section 1.1.3).
- Put a small nut of grease on a finger.

- Put a **THIN FILM** of grease around each piston.

- Turn the two big pistons (waste pistons) with the help of the key provided in the installation kit.
- Keep on putting a thin film of grease around each piston.
- The other pistons can be turned with fingers.

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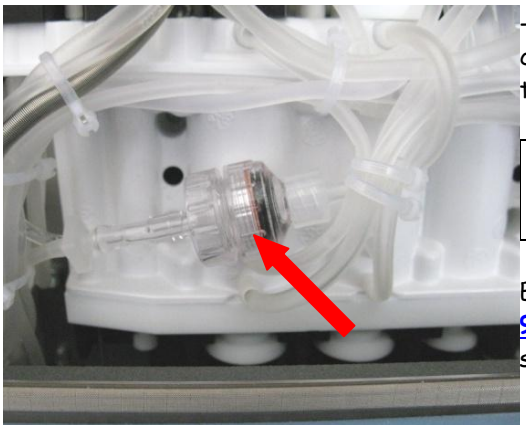
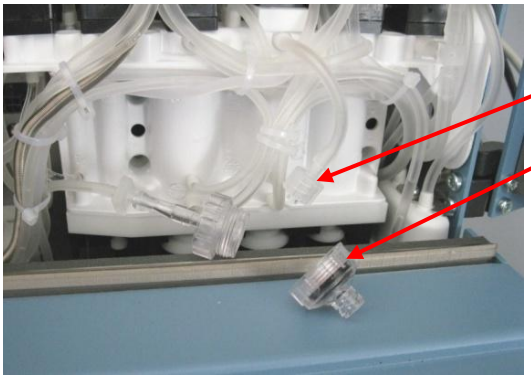
9.1.4 In line filter cleaning



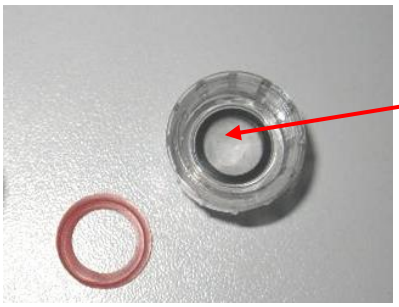
- The in line filter allows to eliminate the small pieces of rubber cap which could be generated in case of multiple sampling of the same sample or if the rubber cap quality is poor.

	Wear rubber gloves and wash hands with a disinfectant after completion of work.

Exchange or clean the filter following the maintenance table (see section 9.1.1) or when the message "**NEEDLE RINSING DEFAULT**" appears (see section 9.5.2).



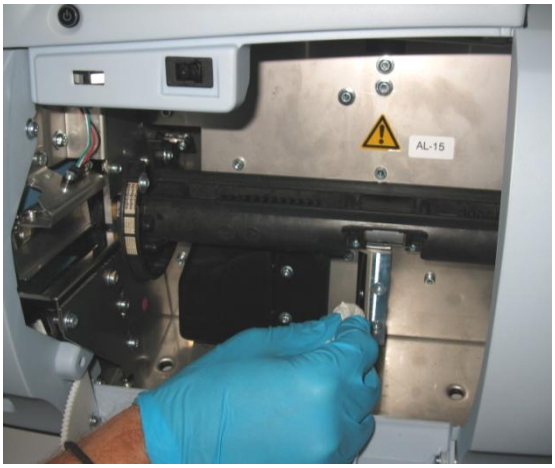
- Disconnect the luer connector and let the other tubing connected on the filter.
- Unscrew the luer part of the filter from the part remaining fixed.
- Always open the filter after the disconnection of the luer to avoid losing the o-ring.



- The filter is dismountable and cleanable.
- Unscrew the two parts of the filter, remove the o-ring, and clean the part with the grid under water (the grid is fixed with the part).
- Reassemble with the two parts and screw the two parts completely.

	If the o-ring is missing or if the filter is not completely screwed, the MYTHIC 22 AL will stop with a pressure alarm "NEEDLE RINSING DEFAULT" (see section 9.5.2).

9.1.5 Barcode cleaning



- Open the front door only when the light is green (see section 5.6.8)

	Be careful with laser light of the barcode reader, if the red light is present during the opening of the door, close it, switch off the AL and call Orphee representative. The barcode reader is a laser CLASS II, never dismantles the cover; in case of problem call Orphee representative.

- Clean the mirror of the barcode reader with soft paper and a glass cleaner.

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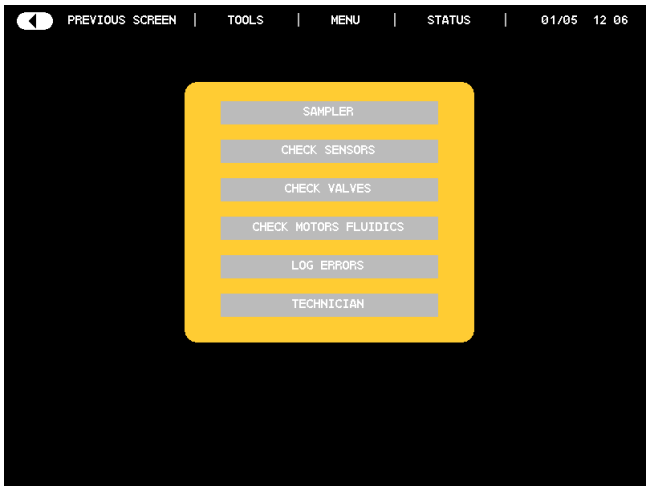
9.2 CLEANING CYCLES

- To have access to the **hydraulic cycles**, press SERVICE from the **MAIN MENU**, then press:

- DRAIN ALL To drain the counting baths, the flow cell and the waste syringes,
- RINSE ALL To fill the counting baths, the flow cell and the waste syringes,
- CLEANINGS To perform a cleaning of the aperture blocks and the flow cell with the cleaner,
- BACKFLUSH APERTURE To perform a back flush in the aperture blocks,
- BACKFLUSH OPTICS To perform a back flush in the flow cell,

9.3 TROUBLESHOOTING SCREEN

- To have access to this cycle, press SERVICE from the **MAIN MENU**, then press TROUBLESHOOTING



NOTA: TECHNICIAN is only available to the Orphee's service people.

- The function of each button is described in the sections hereafter (9.3.1 to 9.3.5):

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9.3.1 Sampler

NOTA: To understand the function of each button we recommend to follow an Orphee's training.

9.3.2 Check sensors

- This screen allows checking if the different sensors are available in case of problem.

NOTA: To understand the function of each sensor we recommend to follow an Orphee's training.

- Range of trigger temperature:
  - Ambient: 17°C <--> 35°C
  - Enclosure: 32°C <--> 40°C
  - Reagents: 34°C <--> 45°C
- The four buttons located at the bottom of the screen allow checking: the HB led, the optical led, the aperture current and the pump. For testing, press the button, check the function, then press again the button.

9.3.3 Check valves

- For testing the valve, press the dedicated button to switch the valve on, then press again to switch it off.
- At each pressing, a click (noise) can be heard, if nothing is heard, call an Orphee's representative.

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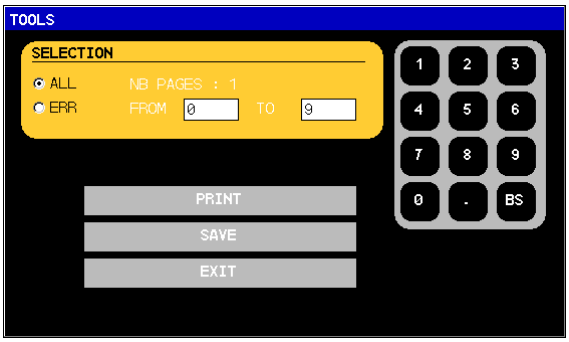
9.3.4 Check motors fluidics

Each motor of the fluidics part is tested during a short cycle. If one or several motors are in default, the associated prompts will be displayed.
In case of problem, call your Orphee's representative.

9.3.5 Log errors

- This screen allows visualizing the date and timing when an error has occurred, as well as the code and the origin of this error.

- To print a part of or all the errors press **TOOLS**.

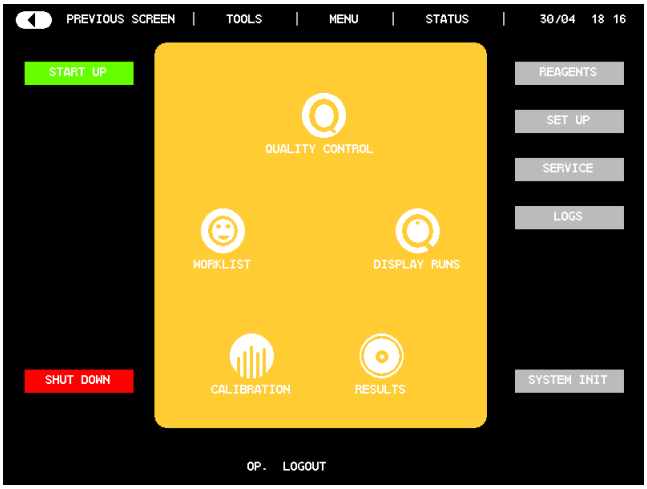


To print or save (on an USB key) the errors, select **ALL** for all the pages (the number appears at the right) or select **ERR**, then the starting number and the ending number.

9.4 REPAIRING

After opening any doors or dismantle any parts, for performing a cleaning or a repairing, take attention with all metal sheets which can injure your fingers.

9.4.1 Emergency stop



In case of mechanical or hydraulic problem, immediately press , the **MYTHIC 22 AL** will make an emergency stop.

- After having identified the problem (see section 9.5), it is necessary to perform a system initialization by pressing **SYSTEM INIT** or accede to this cycle by pressing **SERVICE** from the **MAIN MENU**.

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- To perform the system init press

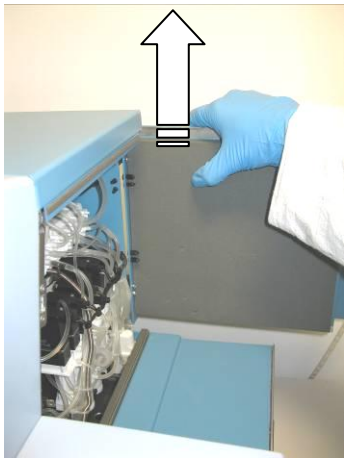
SYSTEM INIT

- This cycle allows reinitializing all the motors, unloads the racks which remain in the sampler, clean and rinse all the fluidics part.

- After this initialization, the work may continue.

9.4.2 Needle or o-ring replacement

	Wear rubber gloves and wash hands with a disinfectant after completion of work. **The replacement of the o-ring is <u>MANDATORY</u> for each disassembling of the needle.**



- Open the door on the right side by unscrewing the two quarter turn screws with the key provided in the kit.
- Open completely the door, and then lift it to remove.

- The needle is in front of the counting chambers

- First remove the top of the needle from the clip, leave the needle free in front of the clip (do not pull a lot the upper needle).

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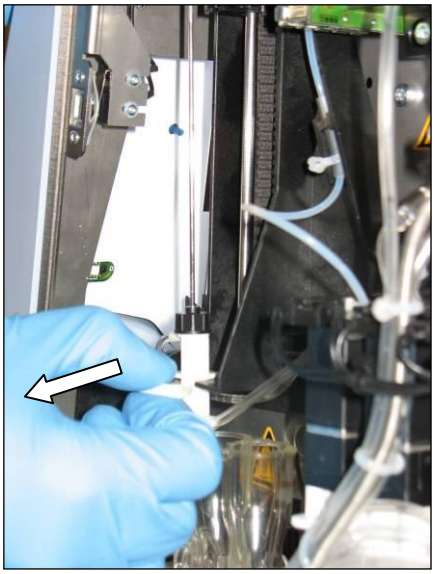
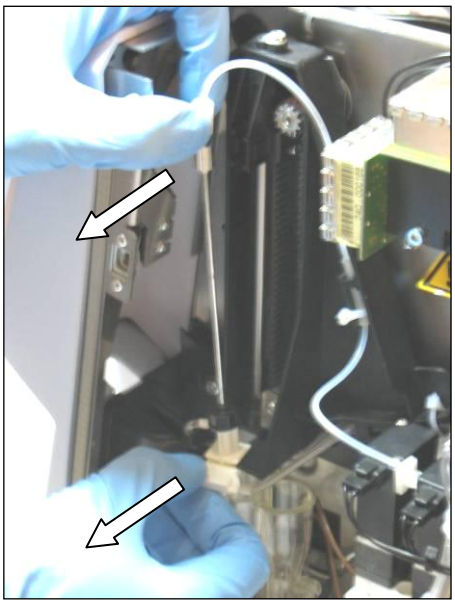
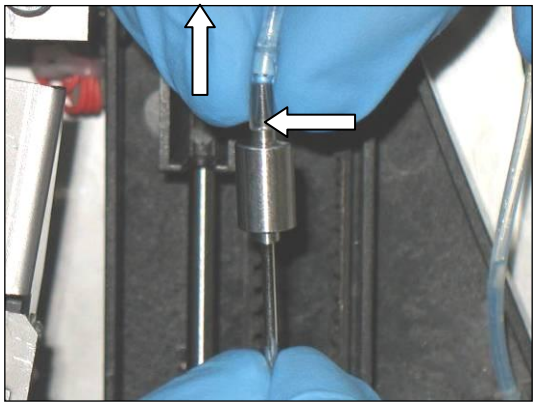


- Remove the sampling module, while slightly lowering the clip to the bottom.



- Pull the needle and the rinsing head system towards outside.



- Remove the tubing fixed at the end of the needle <u>only if you want to change the needle</u>.

- Leave the tubing connected if you only change the o-ring.

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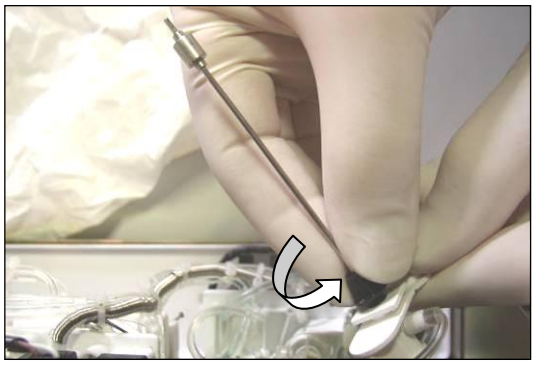
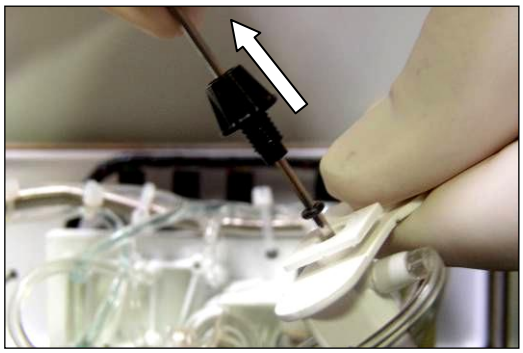
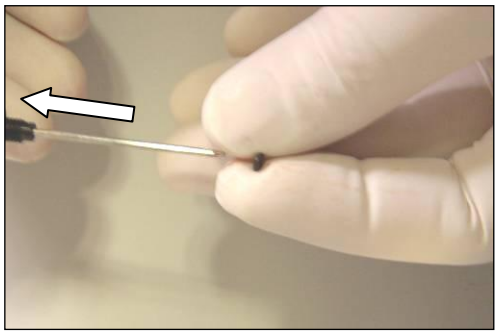


- Unscrew the serrated roller which maintains the seal and the needle.



- Raise up together the serrated roller, the needle and the o-ring from the rinsing head.



- Remove the o-ring.
- Replace the needle and/or the o-ring.

	Only grease and <u>lightly</u> the o-ring between your fingers. If the needle is greased, the grease could block the grooves and create diluent leak and the results would be altered.

<u>REASSEMBLY PROCEDURE</u>:
To reassemble the unit, carry out the various operations in the opposite direction. Place the seal on the needle gently in order not to wound it.

	Do not grease the needle after removing. If the needle is greased, the grease could block the grooves and create diluent leak and the results would be altered.

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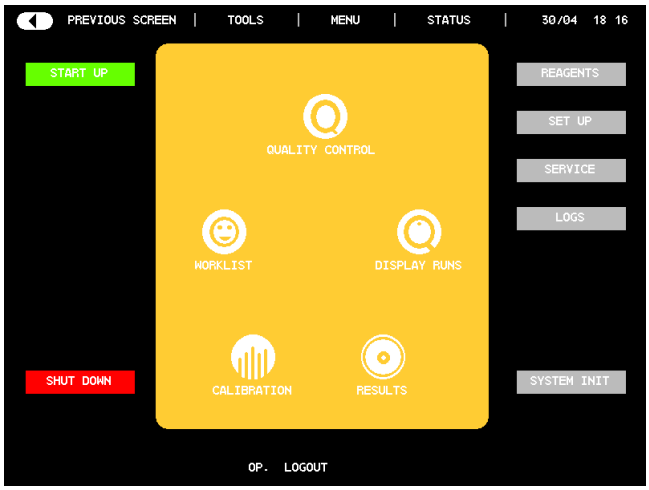
9.4.3 Baths dismantling

This procedure must be carried out to replace the bath seals on the manifold or the aperture seals.

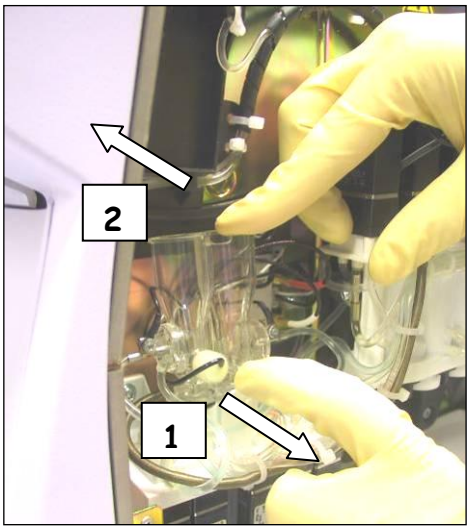
	Wear rubber gloves and wash hands with a disinfectant after completion of work.



- From the **MAIN MENU**, press SERVICE,

- Then press DRAIN ALL.

- The WBC and RBC bath will be emptied.



- To remove the counting bath module, pull the clip 1 while pushing the top from the counting bath towards the inside of the machine 2.

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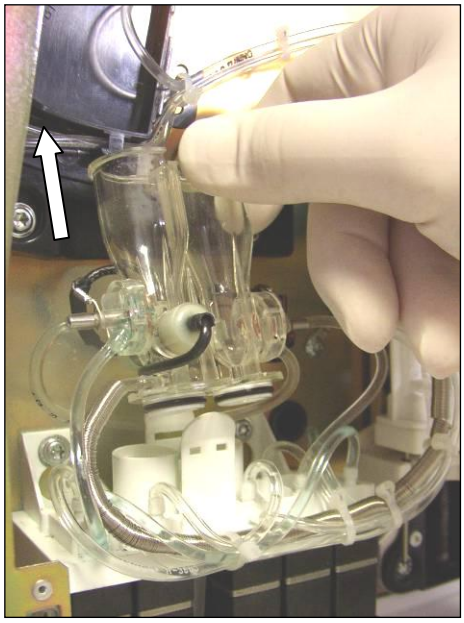
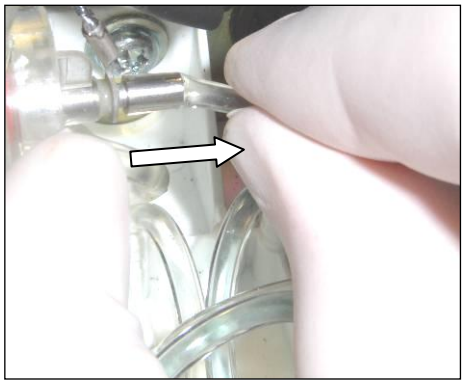
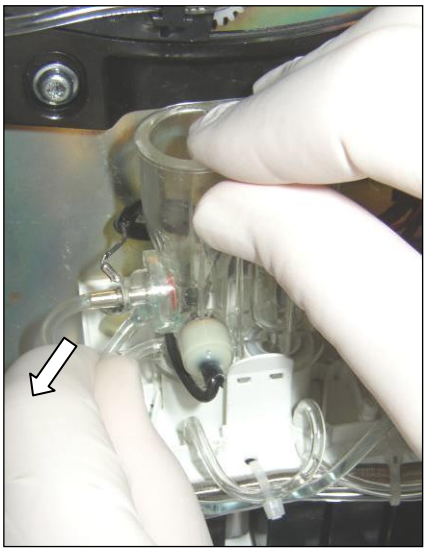


- Then, upwards, raise the counting module.



- Next, remove the tubing fixed on the RBC counting head, located on the right side of the counting module. Leave the sheath on the tubing.



- Remove the tubing fixed on the plastic fitting located under the stainless tube from WBC counting block. Leave the sheath on the tubing.

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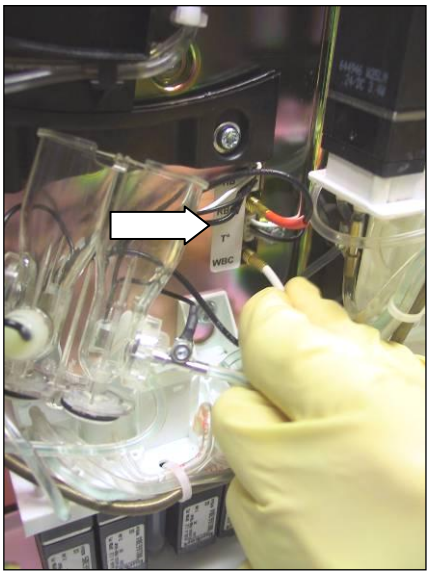


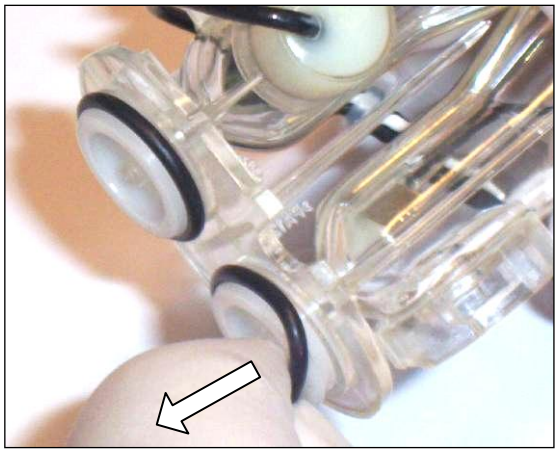
- Remove all connectors.

- The counting bath module can now be handled to carry out the required operations of replacement.

REASSEMBLY PROCEDURE :
To reassemble the unit, carry out the various operations in the opposite direction. Do not forget to put the sheaths back on the tubing.

9.4.4 Baths o-ring replacement

	Wear rubber gloves and wash hands with a disinfectant after completion of work.



- Before performing the operation, drain the baths and dismantle the counting bath block (see section 9.4.3).

- Replace the o-ring and/or the complete bath block.

REASSEMBLY PROCEDURE :
To reassemble the unit, carry out the various operations in the opposite direction.
Place the seal on the counting bath gently in order not to wound it.

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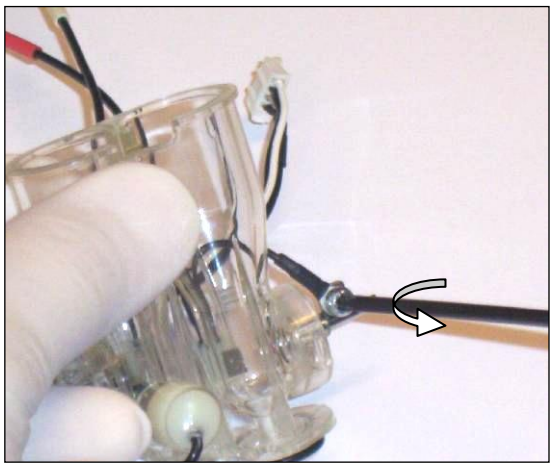
9.4.5 Aperture block replacement

	Wear rubber gloves and wash hands with a disinfectant after completion of work.

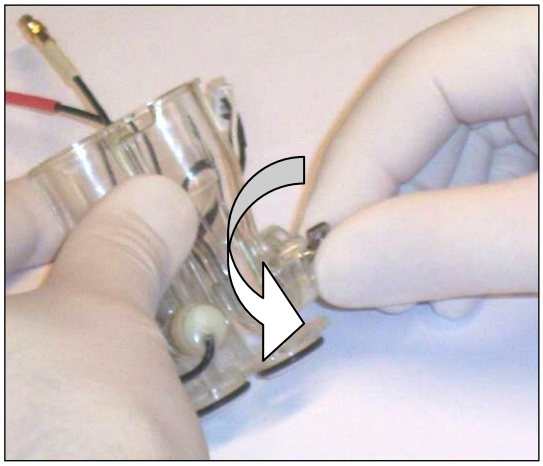


- Before performing the operation, drain the baths and dismantle the counting bath block (see section 9.4.3).

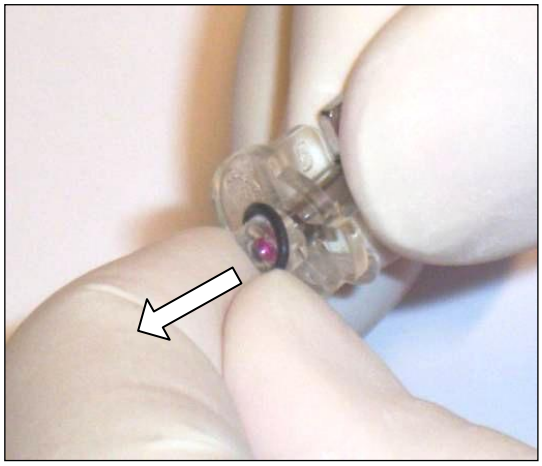
- Remove the tubing from the blocks to be replaced.

- With the tool provided in the maintenance kit, unscrew the screw and remove the connection.

NOTA: This operation can be performed without dismantling the complete bath block.



- Unscrew the aperture block a quarter of turn.



- Remove the o-ring and replace it by a new one or replace the whole part.

NOTA: The WBC aperture block is marked with a figure **8** on the ear and with a figure **5** for the RBC.
Do not grease the aperture o-ring.

REASSEMBLY PROCEDURE :

To reassemble the unit, carry out the various operations in the opposite direction.
Place the seal on the aperture block gently in order not to wound it.

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9.5 TROUBLESHOOTING OCCURENCES

	In any case, if a problem is not solved, call your Orphee's representative.

9.5.1 Analytical problems

PARAMETERS	PROBLEMS	CONDITIONS	SOLUTIONS
WBC	No result	No HGB	Check the lysis level. Check the right lysis tubing connection to the WBC bath. Check the valve No 9.
		HGB OK	Check the bath wires. Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful. Change the aperture block if unsuccessful.
	Bad stability		Perform a Back flush and a Cleaning Cycle and then a Bleach cycle if unsuccessful. Check the level bubble flow in the WBC bath during the run cycle. Check the reagent and enclosure temperature.
5 DIFF	No result or bad stability	No HGB & WBC	Check the lysis level. Check the right lysis tubing connection to the WBC bath. Check the valve No 9.
		HGB & WBC OK	Perform a Back flush Cycle and then a Bleach cycle if unsuccessful. Check the valves No 12, 13, 16 & 17. Check the reagent and enclosure temperature. Check the preampli connection wires.
	Rejection	*	Check the results on blood smear.
RBC	No result	No HCT & PLT	Check the bath wires. Perform a Cleaning Cycle and then a Bleach cycle if unsuccessful.
	Bad stability	HCT & PLT	Perform a Back flush and a Cleaning Cycle and then a Bleach cycle if unsuccessful. Check the bubble flow level in the RBC bath during the run cycle. Check the bubble flow level in the WBC bath during the first dilution.
HGB	No result		Check the led light on
	Bad stability		Check if no bubble in the lysis tubing. Check the reagent and enclosure temperature. Check the bubble flow level in the WBC bath during the run cycle.
	Rejection	--- *	Close the door. Perform a new Start Up cycle.
	Flag **INS_H**		Close the door. Perform a new Start Up cycle.
ALL	Bad results		Check the diluent level and if the tubing is pinched. Check if the diluent container is at the same level as the analyzer.

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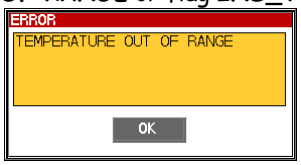
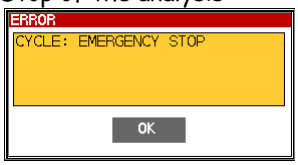
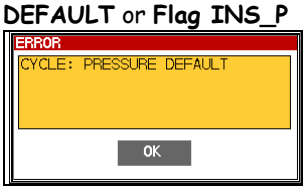
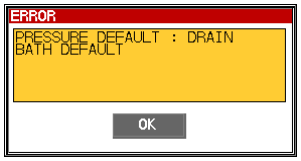
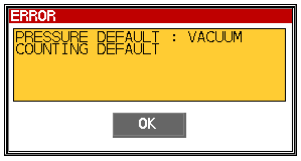
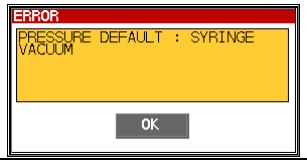
9.5.2 Other problems

ORIGIN	PROBLEMS	SOLUTIONS
ANALYZER	Diluent leaks around the needle during the run cycle	Check the rinsing needle block (presence of clots) and clean it if necessary. Clean the needle by removing the grease in the grooves, see section 9.4.2
	No starting	Check the power supply connection wires
	No display	Check the flat cable.
	ID and/or PID typing impossible	ID and/or PID are mandatory (see section 3.4.3).
	Message : **TEMPERATURE OUT OF RANGE** or flag **INS_T** 	Check the origin of the problem of temperature in section 9.3.2. Trigger temperature values: Ambient: 17°C <--> 35°C Enclosure: 32°C <--> 40°C Reagents: 34°C <--> 45°C
	Stop of the analysis 	Proceed as stated hereafter for all prompt starting with **CYCLE**. Wait the complete stop of the sampler (the red LED becomes green) then Perform a **SYSTEM INIT** (MENU/SERVICE) if the problem remains, call your Orphee's representative.
	Message: **CYCLE: PRESSURE DEFAULT** or **Flag INS_P**    	Cases of occurrence (each case has his dedicated prompt): **NOTA**: For all these occurrences, also check the level of the reagents. - **NEEDLE RISING DEFAULT**: check the in line filter locking (see section 9.1.4) and the pump operation. - **DRAIN BATH DEFAULT**: check the tubing connection of the fluidics. - **VACUUM COUNTING DEFAULT**: perform a piston greasing (see section 9.1.3) and check the tubing connection of the fluidics. - **SYRINGE VACUUM**: perform a piston greasing (see section 9.1.3) and check the tubing connection of the fluidics.

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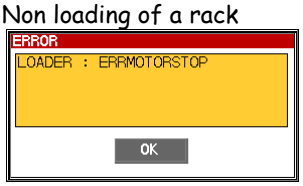
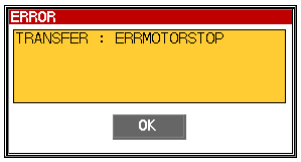
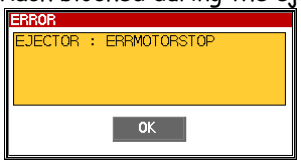
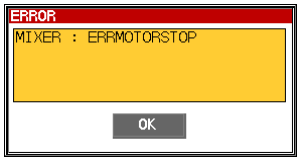
SAMPLER	No Barcode reading	Wait for the end of the in progress cycle, then open the front door and clean the mirror (see section 9.1.5)
	Non loading of a rack  	Proceed as stated hereafter for all prompt starting with **LOADER**: Check if the rack is in the good loading position and if the round label and the barcode label are present and clean (see section 5.6.6.2) If the problem remains, call your Orphee's representative.
	Rack blocked  	Proceed as hereafter for all prompt starting with **TRANSFER**: Perform a **SYSTEM INIT** (MENU/SERVICE) if the problem remain call your Orphee representative.
	Rack blocked during the ejection.  	Proceed as stated hereafter for all prompt starting with **EJECTOR**: Remove all the racks present on the unloading part then run a **SYSTEM INIT** (MENU/SERVICE) if the problem remains, call your Orphee's representative.
	Mixer blocked  	Proceed as stated hereafter for all prompt starting with **MIXER**: Perform a **SYSTEM INIT** (MENU/SERVICE) if the problem persists, open the front door (see section 5.6.8) and check if the mixer can move easy from top to low position (nothing as tube, should breach the movement) then close the door and perform a **SYSTEM INIT** (MENU/SERVICE) if the problem remains, call your Orphee's representative.
	Rack is ejected directly without blood sampling	The barcode of the rack is missing or altered; check the quality of the label and change it, if necessary.

NOTA	In any case of problem generated by the printer, read the printer's operator's manual.

PRINTER	No printing	Check if the printer is selected (see section 3.3) Check the paper level. Check the electrical connection.
	Bad printing	Check the ink ribbon or the ink cartridge.

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9.6 TROUBLESHOOTING MESSAGE

This section allows knowing what to do when a troubleshooting message appears on the screen.
If the problem remains contact your Orphee's representative.

MESSAGE	ACTION
BACKUP : FOLDER NOT FOUND	Re-start the Mythic.
BACKUP: BAD FOLDER DUPLICATION	Re-start the Mythic.
BACKUP: CALIBRATION HISTORY IS FULL	Delete the calibration results.
BACKUP: FAIL TO SAVE RESULT ONTO THE EXTERNAL STORAGE DEVICE. THE INTERNAL MEMORY IS USED.	Check if the USB thumb drive is connected to the analyzer.
BACKUP: FILE SYSTEM FAILED.	Re-start the Mythic.
BACKUP: LAST QC RESTORED.	File has been restored to previous state
BACKUP: LAST RESULT SAVED.	Memory full, next result will not be saved. You have to delete results.
BACKUP: LAST RESULTS RESTORED.	File has been restored to previous state
BACKUP: LAST SETUP RESTORED.	Indicate that your SETUP has been restored
BACKUP: MEMORY IS ALMOST FULL. PLEASE DELETE RESULTS.	Delete results
BACKUP: NO MEMORY AVAILABLE FOR STORAGE	Delete the stored results.
BACKUP: PARTIAL CALI. RES. DELETED.	A bad Result storage occurred.
BACKUP: PARTIAL NUM DELETED.	A bad Result storage occurred.
BACKUP: PARTIAL QC RES. DELETED.	A bad Result storage occurred.
BACKUP: PARTIAL REPET. RES. DELETED.	A bad Result storage occurred.
BACKUP: QC HISTORY IS FULL	Delete the Q.C. results of the ongoing lot.
BACKUP: REPAIR SECTOR DONE.	Internal database as been restored after detecting incoherence.
BACKUP: REPEATABILITY HISTORY IS FULL	Delete the repeatability results.
BACKUP: SECTOR FAILED.	Hardware failure on memory
BACKUP: SETUP UPDATED WITH DEFAULT VALUES.	Indicate that your SETUP has been released.
BACKUP: SYSTEM ERROR	Re-start the Mythic.
CLEAN NOT DONE	Perform a CLEANING.
CLEANER ALMOST EMPTY	Replace the bottle and perform a prime Cleaner.
COM: BAD CYCLE MODULE	Rebuild cycles with good options.
COM: CRC CONTROL ERROR	Communication errors re-try.
COM: SIZE ERROR.	Try again, if the problem occurs, call an Orphee's representative.
SYSTEM INIT NOT DONE	Perform a SYSTEM INIT.
CYCLE: PUMP COMMAND FAILED.	Check the pump connection.
CYCLE STOPPED BY USER	Emergency stop, please perform a SYSTEM INIT.
CYCLE: BUSY	Wait before performing a cycle.
CYCLE: CMD VALVE FAILED	Change the valve
CYCLE: EMERGENCY STOP	Perform a SYSTEM INIT.
CYCLE: FLUIDIC DOOR OPENED	Close the Fluidic door. Run SYSTEM INIT.
CYCLE: HGB CHANNEL SATURATION. PLEASE RUN STARTUP.	Run Startup Cycle. If the problem still occurs, call an Orphee's representative.
CYCLE: INIT NOT DONE	Perform an initialization or a SYSTEM INIT.
CYCLE: PRESSURE DEFAULT	May occur by leak of reagent or check tubing in the fluidics.
CYCLE: VALVE "X" FAILED	Change the valve
DILUENT ALMOST EMPTY	Replace the container and perform a prime Diluent
HARDWARE: A.L.L BOARD ID FAILED.	Check the hardware connection on ALL Board
HARDWARE: F.S.C BOARD ID FAILED.	Check the hardware connection on FSC Board
HARDWARE: FAN FAILED.	Check if your temperature fan is running.
HARDWARE: HEAT ENCLOSURE FAILED.	Call an Orphee's representative.
HARDWARE: HEAT ENCLOSURE STOPPED.	Check your enclosure sensor.
HARDWARE: HEAT REAGENT FAILED.	Call an Orphee representative.
HARDWARE: HEAT REAGENT STOPPED.	Check your reagent sensor.
HARDWARE: SYSTEM ERROR	Re-start the Mythic.
HEATING IN PROGRESS, PLEASE WAIT.	Wait for the system to reach its temperature.
ID AND/OR PID MANDATORY (CHECK SETUP). SID ALWAYS MANDATORY.	Enter an ID and/or PID and SID.
INIT PRINTER	Switch on the printer or invalidate the printings.
INTERN: COUNT ERROR	Re-start the Mythic.

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MESSAGE	ACTION
INTERN: MEMORY CORRUPTED	Re-start the Mythic.
INTERN: NO MEMORY AVAILABLE	Re-start the Mythic.
INTERN: RESULT AREA IS LOCKED	Wait before performing a cycle. If persisting, re-start the Mythic.
INVALID DATA FORMAT.	Check the data format
LOT ALREADY EXISTS. ACTION CANCELLED.	Select another lot.
LYSE ALMOST EMPTY	Replace the bottle and perform a prime Lysis
MECA: HOME NEEDLE NOT FOUND	Perform a SYSTEM INIT
MECA: HOME ROCKER NOT FOUND	Perform a SYSTEM INIT
MECA: HOME SYRINGE NOT FOUND	Perform a SYSTEM INIT
MECA: MOTOR NEEDLE BUSY	Re-start the Mythic.
MECA: MOTOR NEEDLE GAP	Nothing to do
MECA: MOTOR ROCKER BUSY	Re-start the Mythic.
MECA: MOTOR ROCKER GAP	Nothing to do
MECA: MOTOR SYRINGE BUSY	Re-start the Mythic.
MECA: MOTOR SYRINGE GAP	Perform a pistons greasing.
MECA: NEEDLE NOT IN TOP POSITION	Perform a SYSTEM INIT.
LOADER: MOTOR HOME NOT FOUND	Perform a SYSTEM INIT
LOADER: MOTOR BUZY	Re-start the Mythic.
LOADER: ERR MOTOR GAP	Nothing to do
LOADER: ERR MOTOR STOP	Perform a SYSTEM INIT
TRANSFER: MOTOR HOME NOT FOUND	Perform a SYSTEM INIT
TRANSFER: MOTOR BUZY	Re-start the Mythic.
TRANSFER: ERR MOTOR GAP	Nothing to do
TRANSFER: ERR MOTOR STOP	Perform a SYSTEM INIT
MIXER: MOTOR HOME NOT FOUND	Perform a SYSTEM INIT
MIXER: MOTOR BUZY	Re-start the Mythic.
MIXER: ERR MOTOR GAP	Nothing to do
MIXER: ERR MOTOR STOP	Perform a SYSTEM INIT
EJECTOR: MOTOR HOME NOT FOUND	Perform a SYSTEM INIT
EJECTOR: MOTOR BUZY	Re-start the Mythic.
EJECTOR: ERR MOTOR GAP	Nothing to do
EJECTOR: ERR MOTOR STOP	Perform a SYSTEM INIT
NETWARE: SERVER INIT. FAILED	Check your analyzer configuration
NETWARE: CLIENT INIT. FAILED.	Check your analyzer configuration
NO PRINTER RESPONSE	Switch on the printer or invalidate the printings.
NO PRINTER SELECTED	Switch on the printer or invalidate the printings.
NO PRINTER SELECTED	Switch on the printer or invalidate the printings.
NUMBER MAX. OF FILES REACHED. PLEASE DELETE FILES.	Delete data on the selected directory.
OUT OF RANGE	Modify the value
PRINTER DRIVER UPDATE FAILED. THE CHOSEN DRIVER IS NOT COMPATIBLE WITH THE MYTHIC SYSTEM.	Select the right driver compatible with the Mythic.
PRINTER ERROR	Switch on the printer or invalidate the printings.
PRINTER IS BUSY	Switch on the printer or invalidate the printings.
PRINTER IS OFF	Switch on the printer or invalidate the printings.
PRINTER: NO PAPER	Add some paper.
RINSE NOT DONE	Perform a clean cycle.
RS232: ACK ERROR	Re-start the Mythic.
RS232: INTERNAL ERROR	Re-start the Mythic.
RS232: SYNCHRO ERROR	Re-start the Mythic.
RS232: TIME OUT	Re-start the Mythic.
RUNNING AUTO CLEANING	Press OK.
SET TEMPERATURE REACHED.	The instrument is ready to work,
SETUP: MODIFICATION NOT ALLOWED.	You have to be logged with the good access code.
START UP CYCLE NOT DONE	Perform a start up cycle.
STARTUP CYCLE FAILED	Perform a new start up cycle.
SYSTEM LOCKED HEATING FAILED	Call an Orphee's representative.
SYSTEM: DOWNLOADING NEW VERSION. PLEASE WAIT	System is resetting after the version is released.
SYSTEM: EEPROM COM ERROR	Re-start the Mythic.

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MESSAGE	ACTION
SYSTEM: FATAL ERROR	Re-start the Mythic.
SYSTEM: INTERNAL TIME OUT	Re-start the Mythic.
TEMPERATURE OUT OF RANGE	Room temperature out of range (<18 or >34°C).
THE CLEANER USED IS OUT OF DATE.	Replace the bottle and perform a prime Cleaner
THE DILUENT USED IS OUT OF DATE.	Replace the container and perform a prime Diluent
THE LYSE USED IS OUT OF DATE.	Replace the bottle and perform a prime Lysis
USB: DIRECTORY DOES NOT EXIST.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: DIRECTORY IS NOT EMPTY.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: EMPTY FILE	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: THUMB DRIVE I/O ERROR.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: THUMB DRIVE IS FULL.	No memory available in USB for storage. You have to delete some data to work.
USB: THUMB DRIVE IS NOT PRESENT.	Connect an USB thumdrive.
USB: TOO MANY FILES OPENED.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO CREATE DIRECTORY.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO OPEN DIRECTORY.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO OPEN FILE	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: WRITE PROTECTED FILE.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
VERSION RELEASE FAILED. THE CHOSEN RELEASE IS NOT COMPATIBLE WITH THE MYTHIC 22 AL SYSTEM.	Select the correct version.
WASTE ALMOST FULL	Replace the waste container
USB: DIRECTORY DOES NOT EXIST.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: DIRECTORY IS NOT EMPTY.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: EMPTY FILE	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: THUMB DRIVE I/O ERROR.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: THUMB DRIVE IS FULL.	No memory available in USB for storage. You have to delete some data to work.
USB: THUMB DRIVE IS NOT PRESENT.	Connect an USB thumdrive.
USB: TOO MANY FILES OPENED.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO CREATE DIRECTORY.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO OPEN DIRECTORY.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: UNABLE TO OPEN FILE	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
USB: WRITE PROTECTED FILE.	The USB thumdrive has an incompatible tree structure for the analyzer, try another one.
VERSION RELEASE FAILED. THE CHOSEN RELEASE IS NOT COMPATIBLE WITH THE MYTHIC 22 SYSTEM.	Select the right version.
WASTE ALMOST FULL	Replace the waste container

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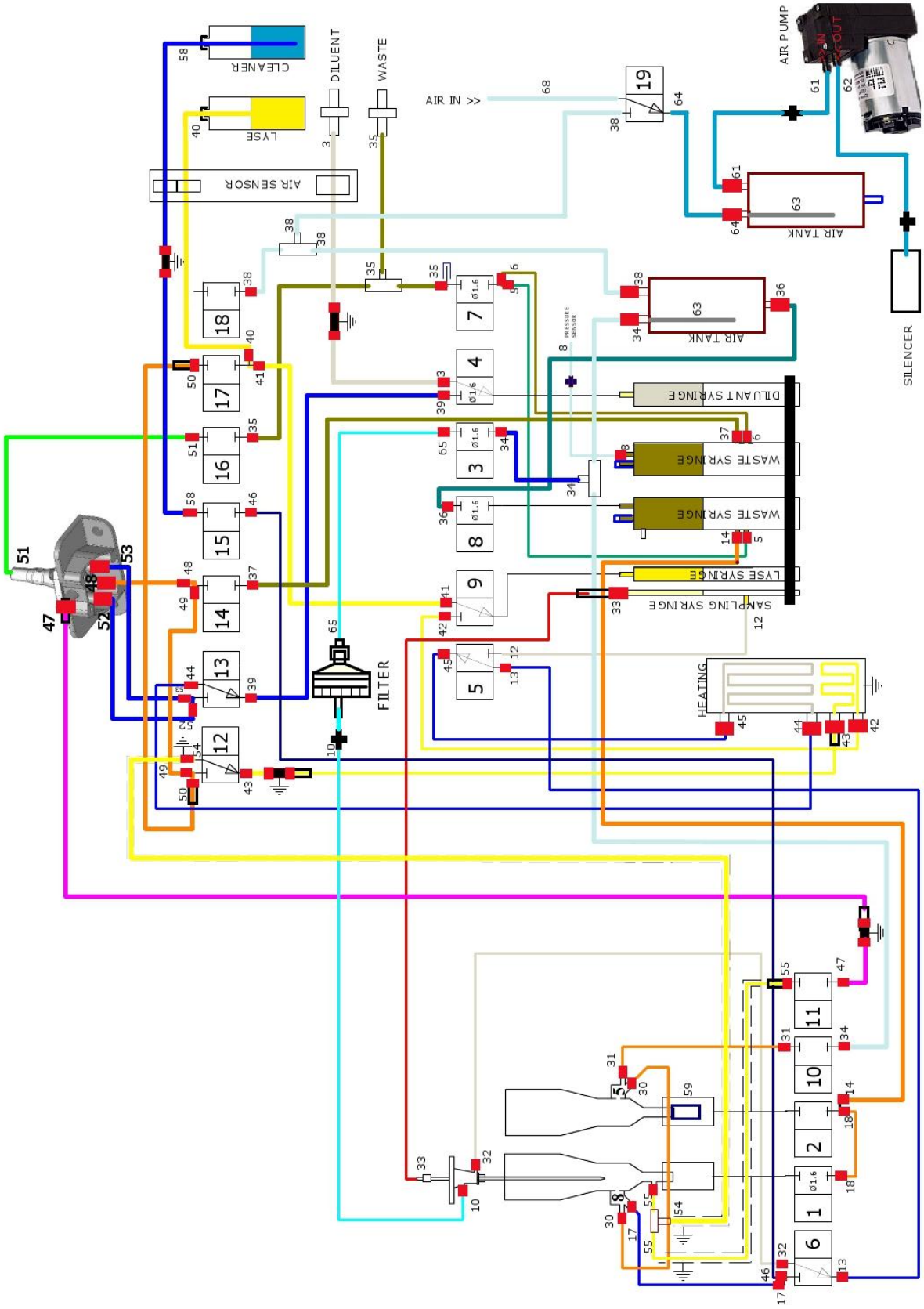
9.7 HYDRAULIC DIAGRAM



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